EFFECTIVENESS OF SWEDISH MASSAGE ON LEVEL OF CHEMOTHERAPY INDUCED NAUSEA AND VOMITING (CINV) AMONG CHILDREN WITH CANCER AT SELECTED HOSPITAL, SURAT, 2015.

DISSERTATION SUBMITTED TO

THE TAMIL NADU DR.M.G.R. MEDICAL UNIVERSIRTY

CHENNAI

IN PARTIAL FULFILMENT OF THE DEGREE OF

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*" **Gratitude** makes **sense** of our past,*
*brings **peace** for today and*
*creates a **vision** for tomorrow."*

LIST OF ABBREVIATIONS

ALL	-	Acute Lymphocytic Leukemia
AML	-	Acute Myeloid Leukemia
AMED	-	Allied and Complementary Medicine Database
ANOVA	-	Analysis of Variance
ASDS	-	Adapted Symptom Distress Scale
BARF	-	Baxter Retching Faces Scale
CNS	-	Central Nervous System
CIN	-	Chemotherapy Induced Nausea
CIV	-	Chemotherapy Induced Vomiting
CINV	-	Chemotherapy Induced Nausea and Vomiting
CINE QOL	-	Chemotherapy Induced Nausea and Emesis Quality of Life
CTC	-	Common Toxicity Criteria
CTZ	-	Chemoreceptor Trigger Zone
CINHAL	-	Cumulative Index to Nursing & Allied Health
DNA	-	Deoxyribo Nucleic Acid
EBSCO	-	Elton B. Stephens Corporation
ESAS	-	Edmonton Symptom Assessment Scale
EMBASE	-	Excerpta Medica data BASE
FACT-G	-	Functional Assessment of Cancer Therapy General
FLIC	-	Functional Living Index Cancer
FLIE	-	The Functional Living Index - Emesis
5-HT3	-	5- Hydroxy Tryptamine
ICCR	-	International Centre for Collaborative Research
ICMR	-	Indian Council of Medical Research
IARC	-	International Agency for Research on Cancer
MANE	-	Morrow Assessment of Nausea and Emesis
MASCC	-	Multinational Association of Supportive Care in Cancer
MDASI	-	MD Anderson Symptom Inventory Core Items
MEDLINE	-	Medical Literature Analysis and Retrieval System Online
NCI	-	National Cancer Institute

NRI	-	Nausea Rating Index
NRS	-	Numerical Rating Scale
NCRP	-	National Cancer Registry Programme
ONI	-	Overall Nausea Index
ORTC	-	Organization for Research and Treatment of Cancer
PBCR	-	Population Based Cancer Registry
RINVR	-	Rhodes Index of Nausea Vomiting and Retching
RN	-	Registered Nurse
SIGLE	-	System for online Grey Literature in Europe
VAS	-	Visual Analogue Scale
VCS	-	Verbal Categorical Scale

LIST OF SYMBOLS

F	-	ANOVA
=	-	Equals to
<	-	Less than
P	-	Level of significance
>	-	More than
%	-	Percentage
+	-	Plus
×	-	Multiplication
n	-	Number of samples
N	-	Total number of samples

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ABSTRACT

Effectiveness of Swedish massage on level of Chemotherapy Induced Nausea and Vomiting (CINV) among children with cancer at selected Hospital, Surat.

Abstract

Aim and objective: To assess the effectiveness of Swedish massage on the level of Chemotherapy Induced Nausea and Vomiting (CINV) among children with cancer. **Methodology:** A quantitative approach, quasi experimental post test only design was adopted to assess the effectiveness of Swedish massage on level of CINV among 60 children with cancer (30 in study and 30 in control group) undergoing chemotherapy, who satisfied the inclusion and exclusion criteria were chosen for the study at Anand Hospital, Surat. Non probability purposive sampling technique was used to select the samples. Swedish massage was performed on the children with cancer at 24 hours and 30 minutes prior to chemotherapy and 24 hours after chemotherapy which was assessed 30 minutes prior to chemotherapy on the first day, 24 and 48 hours after chemotherapy on the second and third day respectively by using Modified Rhodes Index of Nausea and Vomiting. **Results:** The study findings revealed that the post test mean score of level of CINV among children with cancer in the study group was 25.43 with standard deviation of 5.29 and the post test mean score in control group was 125.20 with standard deviation of 7.98. The calculated 't' value was -57.03, which indicated, that there was a high statistical significant difference in the post test level of CINV among children with cancer between study and control group at $p<0.001$ level. **Conclusion:** The results depicted that Swedish massage was effective in reducing the level of CINV among children with cancer receiving chemotherapy and can be practiced as a part of routine nursing care. On completion of the study, Swedish massage was taught to the nurses and caregivers for reinforcing and as an aid for continued practice.

Keywords: *Swedish massage, level of CINV, Modified Rhodes Index of Nausea and Vomiting, Children with cancer.*

INTRODUCTION

The wealth of a nation is not so much in its economical and natural resources but it lies more decidedly in the kind and quality of the wealth of its **children** and youth. Children are the creators and shapers of a nation's tomorrow. They feel a need for physical and mental activity because of developing social sense, imaginative power and intellectual curiosity. Childhood cancer is a global disease; despite the fact that chemotherapy is the gold standard treatment for cancer it has its own side effects which can be mild and temporary but hugely impact the quality of life .The side effects namely are reduced numbers of blood cells, feeling sick -nausea and vomiting, alopecia, tiredness, changes in memory or concentration, mouth or throat problems, eating

problems, bowel changes, skin changes ,numbness or tingling in hands and feet, lymphoedema, body image, infertility, hormonal changes. CINV being the most distressing, extremely unpleasant common side effect of all cancer treatments, it lays a negative impact on the quality of life of children and even refusal to the treatment regimen ultimately leading to death.

Numerous researchers (Cassileth and Vickers 2012;Kutner et al 2011; Post white et al 2012;Hockenberry et al 2012) studied on children coping strategies for CINV to identify anticipatory, acute, and delayed CINV frequency and coping strategies used among pediatric patients with cancer. The most frequently used coping strategies were distraction, music therapy, guided imagery, cognitive distraction, Swedish massage, foot massage, acupressure, yoga, dietary modalities whereas statistically the most effective strategy was concluded to be Swedish massage.

Swedish massage involves administration of combinations of specific manipulations applied in a systematic way, using techniques such as *effleurage, petrissage tapotement, friction and vibration.* Massage benefits for Cancer children are numerous namely they are decreased level of pain, anxiety and fear, increased levels of relaxation, white blood cells and neutrophils, enhanced immune function, decreased depression, increased production of endorphins (natural painkillers), decreased production of stress hormones (cortisol) as highlighted by Tina Allen (2011).

During the clinical postings the investigator observed the complaints of children with cancer receiving chemotherapy were food refusal, decrease fluid intake, decrease urine output, retching, less interaction with other, sweating, anxiety, fatigue and always irritated. Uncontrolled CINV can give rise to medical complications, including poor nutrition, dehydration, electrolyte imbalances, and physical and mental deterioration. The investigator also learnt that there was increasing incidence of children with cancer being treated with chemotherapy facing agony in performing the activities of daily living leading a poor quality of life and strongly felt the need for preventing complication of CINV and rendering a better quality of life and ability to function physically and psychologically well. Thereby the investigator underwent an immense literature search in identifying a supportive and adjunctive nursing intervention in mitigating the side effects

of cancer treatment exploring the effectiveness of Swedish massage as a nursing intervention.

Hence the investigator felt the intense need for employing Swedish massage as an efficient, easy, cost effective and safe nursing intervention for the management of CINV in order to prevent it from developing into life threatening complications compromising patient treatment and survival. Thus it can be performed safely even by nurses and mothers and must be taught to them to be performed as a routine measure.

Objectives

1. To assess and compare the post test level of Chemotherapy Induced Nausea and Vomiting among children with cancer in study and control group.
2. To correlate the post test mean score of Chemotherapy Induced Nausea with Chemotherapy Induced Vomiting among children with cancer in study and control group.
3. To associate the selected demographic variables with the post test mean score of Chemotherapy Induced Nausea and Vomiting among children with cancer in study and control group.

Null hypotheses

NH_1- There is no significant difference between the post test level of Chemotherapy Induced Nausea and Vomiting among children with cancer in study and control group at $p < 0.05$ level.

NH_2- There is no significant correlation of post test mean score of Chemotherapy Induced Nausea with Chemotherapy Induced Vomiting among children with cancer in study and control group at $p < 0.05$ level.

NH_3- There is no significant association of the selected demographic variables with the post test mean score of Chemotherapy Induced Nausea and Vomiting among children with cancer in study and control group at $p<0.05$ level.

METHODOLOGY

A quasi experimental post test only design was adopted to assess the effectiveness of Swedish massage on level of CINV among children with cancer. The independent variable of this study was Swedish massage and the dependant variable was

level of CINV. The study was conducted in Anand Hospital, Surat. The study population includes children with cancer admitted in Anand Hospital, Surat. The sample size consisted of 60 children with cancer (30 in study and 30 in control group) who fulfilled the inclusion and exclusion criteria selected by non- probability purposive sampling technique. The tool used to assess the level of CINV was Modified Rhodes Index of Nausea and Vomiting which assesses the anticipatory, acute and delayed level of Chemotherapy Induced Nausea and Chemotherapy Induced Vomiting and all 3 days level of CINV for three consecutive days.

After thorough preparation before beginning the intervention, the demographic variables were collected using structured interview schedule and medical record review. The investigator arranged the treatment room, with a clean bed, to maintain privacy. The investigator performed the massage with or without the presence of the parents according to the child's choice. The investigator performed hand hygiene and adorned face mask before handling the children following strict aseptic techniques.

The investigator began the Swedish massage by stroking the child from the buttocks up to the shoulder and then moved downward to the buttocks using less pressure. Then the investigator used her thumb to oppose finger, knead and stroke the right half of the back with her right hand, knead and stroke the left half of the back with her left hand. The investigator started from buttocks moved towards the child's shoulder and then again moved down the back. The investigator used fleshy sides (proximal) of her hands lightly stroked the back from the buttocks up to the shoulder and repeated it. Next, the investigator used the thumb pads or fingertips and applied deep, circular movement near joints and other bony areas along the sides of the spine from the buttocks up to the spine of the child. Lastly, the investigator pressed the child on the back and upper limbs, ended by rapidly shaking with mild pressure. The investigator performed Swedish massage for 20 minutes each day - 24 hours and 30 minutes prior to chemotherapy, 24 hours after chemotherapy along with Hospital routine (standard antiemetic drugs).The children with cancer in the control group were allowed to follow the Hospital routine (standard antiemetic drugs). The post test was done 24 hours after each day's intervention for 3 days by using Modified Rhodes Index of Nausea and Vomiting.

RESULTS & DISCUSSION

The findings revealed that 28(93.33%) children with cancer experienced mild level of CINV, 2 (6.66%) children with cancer experienced moderate level of CINV in the study group while 1(3.33%) children experienced great level of CINV and 29 (96.66%) experienced severe level of CINV in the control group .The post test mean score of the study group was 25.43 with standard deviation of 5.29 whereas the post test mean score of control group was 125.20 with standard deviation of 7.98 .The calculated 't' value was -57.03, which indicated, that there was a high statistical significance difference in the post test level of CINV among children with cancer between study and control group at $P<0.001$ level. The comparison of post test mean score of CINV between the study and control group among children with cancer showed that the calculated unpaired 't' test value was -57.03 which shows high statistical significance at $p<0.001$ level.

These values evidence that there was a significant reduction in the level of CINV among children with cancer in study group after providing Swedish massage as a nursing intervention than those who were allowed to follow only the Hospital routine. Thus Swedish massage was proved to be an effective and easy method for reducing the level of CINV among children with cancer.

Thus the null hypothesis NH_1 stated earlier that "**There will be no significant difference between the post test level of CINV among children with cancer in study and control group at $p < 0.05$ level." was rejected.**

The analysis of correlation coefficient between the post test mean score of CIN with CIV in the study group using Karl Pearson correlation revealed that 'r' value of was -0.026 which showed a negative correlation which was significant at $p< 0.01$ level whereas in the control group Karl Pearson correlation revealed that 'r' value of was 0.479 which showed a positive correlation which was significant at $p< 0.01$ level.

Thus the null hypothesis NH_2 stated earlier **"There will be no significant correlation of post test mean score of Chemotherapy Induced Nausea with Chemotherapy Induced Vomiting among children with cancer in study and control group at $p < 0.05$ level" was rejected.**

The study findings were analyzed by means of one way Analysis of Variance (ANOVA). The one way ANOVA 'F' value indicated that there was significant association of post test level of all 3 days CINV with type of cancer in the study group and with age in years in the control group respectively.

Hence the NH_3 stated earlier **"There will be no significant association of the selected demographic variables with the post test mean score of CINV among children with cancer in study and control group at $p<0.05$ level." was rejected.**

CONCLUSION

The aim of the study was to assess the effectiveness of Swedish massage on level of CINV among children with cancer. The findings proved that there was a improvement in reducing the level of CINV among children with cancer in study group who received Swedish massage than those who underwent Hospital routine $t= -57.03$ at $p < 0.001$ level, Thus the study findings provided evidence that Swedish massage was effective in reducing the level of CINV among children with cancer. Therefore the nursing intervention Swedish massage can be utilized by the pediatric health care providers and caretakers in their practice at the oncology wards.

IMPLICATIONS

The pediatric nurses can adopt Swedish massage as an easy, efficient and safe method employed in routine care of children with cancer at their clinical area of practice. The pediatric nurse being a nurse educator can integrate the major study findings in nursing curriculum at various levels to build up and train the students to identify CINV at earliest using Modified Rhodes Index of Nausea and Vomiting and to prevent the complications of CINV. The findings of the study can be disseminated to the nurses working in various institutions and student nurses through various media. The Nurse administrator should instigate organizing CNE, conferences and workshop on various trends of Swedish massage on level of CINV and other potential benefits.

CHAPTER – 1

INTRODUCTION

INTRODUCTION

Children are not only divine gifts but also the mirror of a nation and hope of the world. They are the countries biggest human investment for development. In a developing country like India due to poverty and prevailing socio-cultural milieu a substantial number of school children from pediatric age to adolescents suffer from various diseases which can be prevented if the diagnosis, treatment and preventive measures are taken in time. Health is a key factor in school entry; the school going age is a formative period, physically as well as mentally, transforming the child into a promising adult. Poor health and nutritional status will affect work capacity as well as cognitive functions.

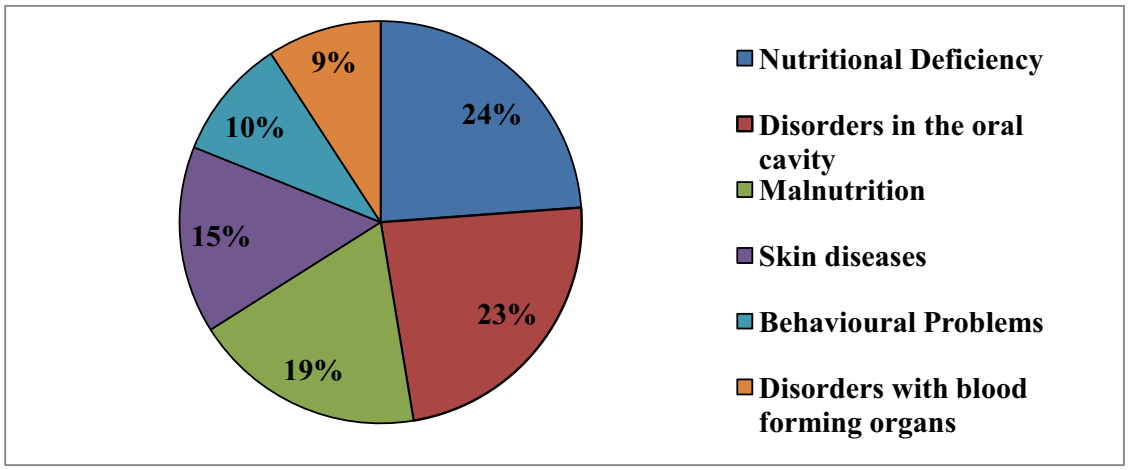

Figure 1.1.1: Major health problems of school age children

Source: The Internet Journal of Epidemiology (2013)

Cancer is the rapid and uncontrolled growth of mutated cells that can affect one or more body systems. Cancer is, by definition, mutant cells. Somewhere in the cell line, a cell had an abnormality in its propagation control and its Deoxyribo Nucleic Acid damage control checkpoints. This allows the cell to propagate without check no matter what damage it accrues. This abnormality happens in two main ways: oncogenes, which cause cell growth and multiplication, and tumor suppressor genes, which prevent excessive cell growth. Cancers occur when either oncogenes are amplified or tumor suppressors are suppressed. Usually, these mutations happen in the cell line, and then cause a tumor to develop in that specific site. Sometimes, these mutations occur when

the embryo forms, known as germ line mutations. These are commonly associated with high incidence of childhood cancer. Most childhood cancers are thought to caused by genetic abnormalities (Le Mone, Burke and Banldoff, 2011).

Cancer is uncommon in children, but can happen, diagnosing cancer at an early stage, greatly improve the chance that a child will survive to live a long life. The most common childhood cancers are leukemia, lymphoma, and brain cancer.

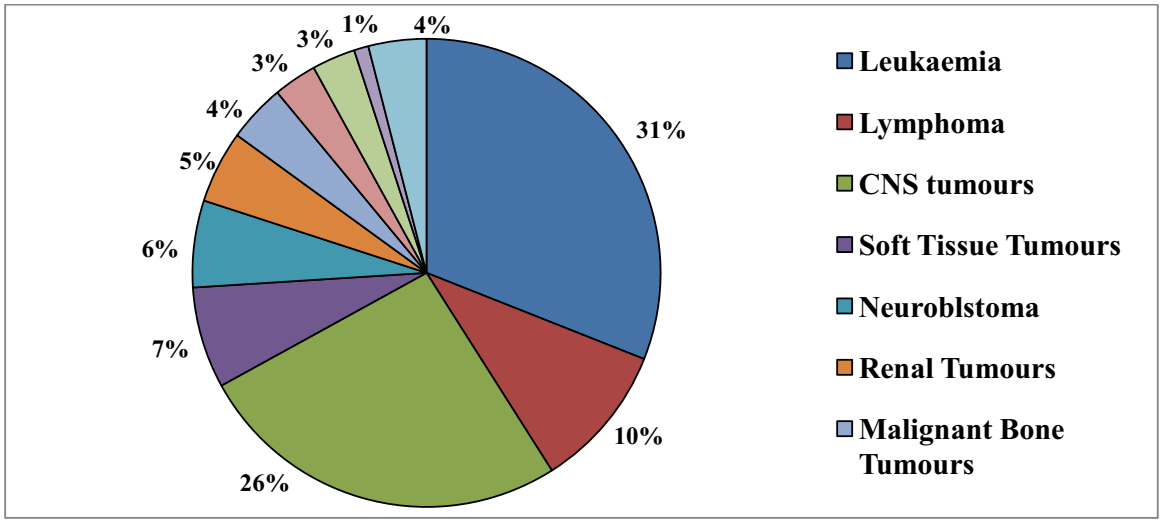

Figure 1.1.2: Types of Childhood Cancers (Age group 0-14 years)

Source: Cancer treatment and survivorship facts and figures (2014-2015)

Children must be watched for changes in health and behavior that come on quickly or will not go away, like those listed below:

C - Continued weight loss that can't be explained.
H - Headaches, often with early morning vomiting.
I - Increased swelling or pain that won't reduce in bones, joints, back or legs.
L - Lump or mass, especially in the abdomen, neck, chest, pelvis, or armpits.
D - Develops a lot of bruising, bleeding or rashes
C - Constant infections.
A - A whitish color behind the pupil.
N - Nausea that won't go away or vomiting without nausea.
C - Constantly tired or unusually pale.
E - Eye or vision changes that come on quickly and won't go away.
R - Recurrent fevers that can't be explained or that won't go away.

Cancer treatment is multifactorial and patient centered. Some treatments are used to treat cancer in a particular area of the body known as local treatments. They include surgery and radiotherapy. Others can treat cancer in more than one part of the body at a time known as systemic treatments. Targeted therapy, hormonal therapy, chemotherapy, organ conservation, generally works in multidisciplinary approach. Regardless of the fact that chemotherapy improves survival; it has its own toxicity and side effects, where in Chemotherapy Induced Nausea and Vomiting (CINV) have a negative impact on the quality of life of children with cancer, (Childhood Cancer Science World News 2014).

CINV is classified into anticipatory, acute and delayed. Anticipatory nausea and vomiting is a learned or conditioned response. It appears to be the result of previous experiences with chemotherapy that led to nausea and vomiting, in which the brain pairs the sights, sounds, and smells of the treatment area with vomiting. It starts as a person prepares for the next treatment, before the chemotherapy is actually given. Acute nausea and vomiting usually occurs a few minutes to hours after the chemotherapy is given. It goes away within the first 24 hours. The worst fact is that it occurs about 5 or 6 hours after chemotherapy. Delayed nausea and vomiting starts more than 24 hours after chemotherapy and is more likely with certain types of chemo drugs, such as cisplatin, carboplatin, cyclophosphamide, and/or doxorubicin. For example, cisplatin-related vomiting is usually worst from 48 to 72 hours after chemotherapy and can last 6 to 7 days. The designation of acute and delayed CINV as distinct is more than mere timing; physiologic differences exist in the pathways involved, the acute CINV appears to be mediated primarily by serotonin pathways and delayed is more mediated substance P pathways. In some cases, children may refuse to continue potentially beneficial cancer treatment because of CINV. The issue of CINV is devastating pertaining to certain type of cancer and with treatment modalities, especially among children receiving chemotherapy for Acute Myeloid Leukemia.

Many types of therapies are included in the multidisciplinary approach to minimize the side effects of chemotherapy. Among all approaches massage therapy is considered as a beneficial therapy which is currently overlooked. Reducing CINV is relevant to nursing because nursing is holistic care; it focuses on caring for patient's physical, emotional, psychological, spiritual and promoting optimal happiness and health.(Miranda L. Ayers 2015). Oncology nurses play a pivotal role in the care of children receiving chemotherapy and are in a prime position to facilitate better care of

children experiencing CINV. Swedish massage being a non invasive, non pharmacological therapy has opened a doorway to new possibilities and accomplishments in the new millennium.

1.1 BACKGROUND OF THE STUDY

Today, cancer is a common household word, with each of us closely associated with at least one near and dear one, family member or a friend, a neighbor or colleague, diagnosed with cancer. Childhood cancer is a global disease, it acts as a major obstacle and affects in every speck of their life. Children are psychologically pulled into the world of stress, anxiety and worries as to why it has occurred to them and drenched in fear how to resolve it. The children physically undergo drastic changes externally such as hair loss, weight loss, changes in skin tone and varied visible changes; internally such as complete metabolic, pulmonary, renal, gastric, hormonal alterations occur. Children undergo extreme agony when they face social stigma especially when their friends refuse to mingle with them .There are over 200,000 cases around the world annually.

Cancer is the second most common cause of death among children aged 1 to 14 years in the United States, next to accidents. In 2015, an estimated 10,380 children (0-14 years) will be diagnosed with cancer and 1,250 will die from the disease. Every day approximately 250 children will die from cancer. One in 330 children will be diagnosed with cancer by the time they are 20 years old. **(**Foundation for Childhood Cancer, 2014).

A special report on childhood cancer was published in "The Society's Annual *Cancer Facts & Figures"* revealed that **around 1 in 285** children will be diagnosed with cancer before the age of 20. The number of central nervous system cancers diagnosed in 2014 among children was 2240 and the number of new cancer cases expected to be diagnosed being 15,780 whereby the children expected to die of cancer were 1,350 in 2014. About **26 %** percentage of childhood cancer was Acute Lymphocytic Leukemia (ALL), the most common cancer in this age group, (American Cancer Society Researchers, 2014).

On the Indian scene, 1.1 million new cancer cases were estimated, indicating India as a single country contributing to 7.8 % of global cancer burden. Mortality figures were 6, 82,830, contributing to 8.33% of global cancer death. In India cancer is the 9th

common cause for the deaths among children between 5 to 14 years of age (National Cancer Registry Programme 2013). Around 1.6 to 4.8% of all cancers among children below 15 years of age are seen in India and the overall incidence of 38 to 124 per million children, per year, is lower than that in the developed world. (Epidemiology of Childhood Cancer in India, Indian J Cancer, 2010).

The reported incidence of pediatric cancer in India in males (39-150 per million children per year) is higher than in females (23-97 per million children per year) in all cancer registries except in North East India. The highest incidence is reported from Chennai and the lowest from rural Ahmadabad. In India, leukemia continues to be the largest contributor to cancer-related mortality in children, (Indian Council of Medical Research, International Agency for Research on Cancer 2013).

In India, 50,000 children diagnosed with cancer undergo chemotherapy treatment at every cancer Hospital in a year,(Population Based Cancer Registry 2011).As cancer cells tend to grow fast and chemotherapeutic drugs kills these fast growing cells, these drugs can affect normal healthy cells, and this damage leads to varied side effects. The exact pathophysiology of CINV is as follows:

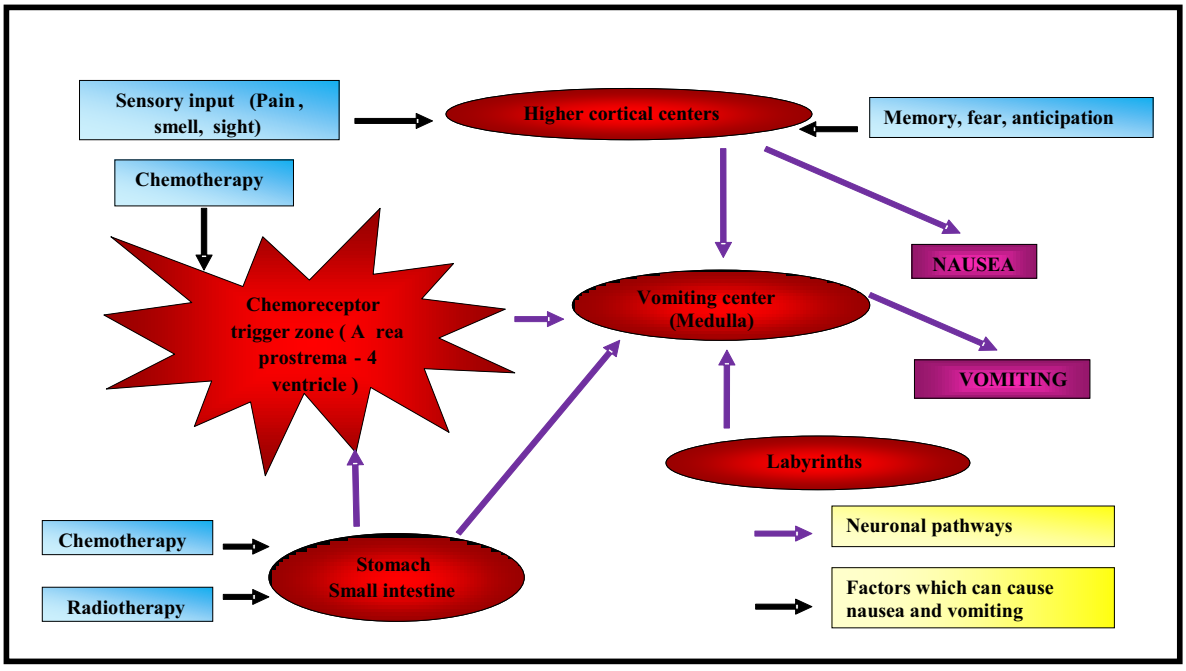

Figure 1.1.2: Neuronal pathways and factors causing CINV

Source: Hesketh et al.N. Engl J Med(2008)

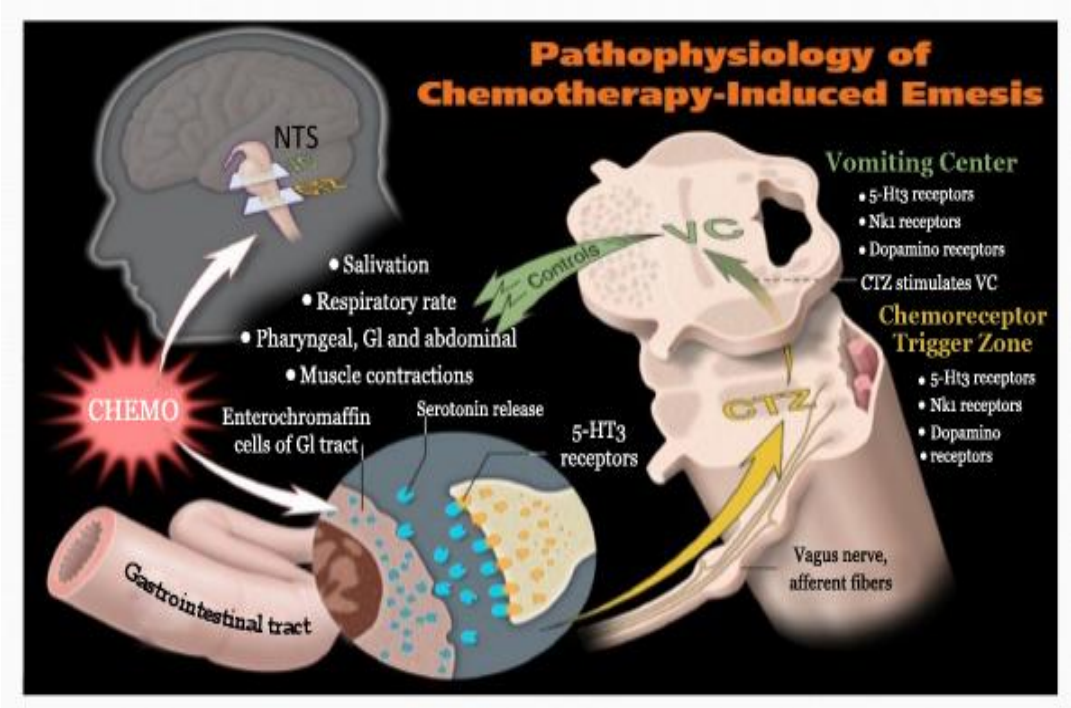

Figure 1.1.3: Pathophysiology of CINV

Source: Katzung B.G, Masters SB, Trevor AJ Basic & Clinical Pharmacology

The sensation of nausea is subjective and act of vomiting are protective reflexes that rid the intestine and stomach of toxic substances. Nausea may be considered a prodromal phase to the act of vomiting. Vomiting consists of a pre-ejection phase, retching, and ejection and is accompanied by shivering and salivation. Vomiting is triggered when afferent impulses from the cerebral cortex, Chemoreceptor Trigger Zone (CTZ), pharynx, and vagal afferent fibers of the gastrointestinal tract travel to the vomiting center, located in the medulla. Efferent impulses then travel from the vomiting center to the abdominal muscles, salivation center, cranial nerves, and respiratory center, causing vomiting. It is thought that chemotherapeutic agents cause vomiting by activating neurotransmitter receptors located in the CTZ, Gastrointestinal tract, and vomiting center. Serotonin (5-HydroxyTryptamine [5-HT_3]) and dopamine receptors are the primary neuroreceptors involved in the emetic response, particularly the 5-HT_3 receptor. (Rudolph M. Navari, 2011)

In Surat, on average, yearly about 80-85% children undergo chemotherapy. The mortality percentage of children undergoing chemotherapy includes 80-100 children. Yearly more than 50,000 children undergo chemotherapy treatment. (PBCR, 2011)

Despite the advances in pharmacological management, standard protocols may not fully alleviate symptoms of CINV in pediatric oncology patients. Investigating the adjuvant role of non-pharmacological interventions is an important consideration of antiemetic therapy. Non-pharmacological measures should be incorporated in conjunction with pharmacological regimes to allow for the effective management of CINV. The use of non-pharmacological measures should be implemented according to the individual needs and circumstances. Some suggested non- pharmacological interventions may include:

Table 1.1.1: Therapeutic Approaches to manage CINV.

S.No.	Therapeutic Approaches	Characteristics
1.	Biologically based practices	Dietary supplements, vitamins, herbal remedies
2.	Mind – body techniques	Meditation, guided imagery, expressive arts (music, art, dance).
3.	Manipulative and body based techniques	Massage, reflexology, exercise.
4.	Energy therapies	Magnetic field therapy, reiki, healing touch, Qi qong.
5.	Ancient medical systems	Traditional Chinese medicine, Ayurvedic medicine, acupressure.

Source: Society of Integrative Oncology (2010).

If these interventions are not brought into practice it leads to uncontrolled CINV which cause pulmonary and metabolic effects, nutritional deficit, dehydration, acute renal failure, esophageal injuries, electrolyte imbalance weakness, and also acquire cross infection and stop children normal activity. These continuing challenges lead to remarkable progress in pediatric cancer treatment and CINV.

The investigator during her clinical experience absolutely captured the above mentioned side effects constricting their normal lifestyle. In order to derive a solution the investigator had felt the need of simple non pharmacological nursing intervention to reduce the level of CINV. Even indepth literature review shows that around 70-80% of the children receiving chemotherapy are at risk of this feasted side effect-CINV,(Miranda L. Ayers 2015) which acts as a background for the investigator to conduct research, to reduce these side effects and comfort the children by using external application (Swedish massage) without any intensified procedure. Learning Swedish massage is technically very easy and requires no equipment but only interest and time. By considering the fact that pediatric nurses are important members of medical healthcare team and have essential role in pediatric cancer care, their practice skills and performances could improve the quality of the care. Therefore, this study was chosen to find the effect of Swedish massage on CINV in pediatric cancer.

1.2 SIGNIFICANCE AND NEED FOR THE STUDY

Cancer is rare but a devastating disease. The most common childhood cancers are leukemia, lymphoma, and brain cancer. As children enter the teen years, osteosarcoma (bone cancer) is more common. The things that cause cancer in children are usually not the same ones that cause cancer in adults; children who have had chemotherapy or radiotherapy are more likely for reoccurrence. In most cases, however, childhood cancers come from random mutations (changes) in the genes of growing cells which happen randomly and unpredictably, there is no effective way to prevent them. However, some symptoms of cancer such as fever, swollen glands, frequent infections, anemia, or bruises can happen with other childhood infections or conditions that are more common than cancer.

Chemotherapy is the medicine that can eliminate cancer cells from our body. Chemotherapy medications are given to children **intravenously, orally, intrathecally**, or into the spinal fluid too. The drugs enter the bloodstream and work to kill cancer cells throughout the body. The duration of chemotherapy, the type and number of different drugs used depends on the type of cancer and how well a child's body responds to the treatment. Every child gets unique treatment, so a child may receive daily, weekly, or

monthly chemotherapy treatments. All chemotherapeutic drugs carry the risk of both short-term and long-term problems.

Table 1.2.1: Problems associated with CINV.

Short term problems	Long term problems
→ Nausea and Vomiting → Hair loss → Fatigue (tiredness) → Anemia, Abnormal bleeding → Menstrual problems	→ Infertility → Growth problems → Hearing loss → Multi organ damage - liver , heart , kidney, skin → Increased risk of other infections and cancers

Source: Evolving Treatment Paradigms for CINV (2012)

CINV has been prevalent since cytotoxic chemotherapy has been used to treat cancer. As it was 20 years ago, CINV is still among the most troubling, feared adverse effect of chemotherapy that children cite most often. It is broadly classified into three types anticipatory, acute and delayed. Anticipatory Nausea and Vomiting is a learned or conditioned response. It occurs to be the result of past experiences with chemotherapy that led to nausea and vomiting, in which the brain pairs the sights, sounds, and smells of the treatment area with vomiting. Acute Nausea and Vomiting usually happens a few minutes to 24 hours after the chemotherapy. Delayed Nausea and Vomiting starts more than 24 hours after chemotherapy. It's more likely with certain types of chemotherapeutic drugs, such as cisplatin as viewed by (Wickham R, 2012).

Poorly controlled CINV has been interfered with the physical and psychosocial consequences including anorexia, malnutrition, fluid and electrolyte imbalances, metabolic changes, decreased functional status, and anxiety as stated by (Dewan, Singhal, & Harit.2010; Hockenberry et al.2012; Vashani et al.2013) . Those issues can make pediatric patients vulnerable to additional complications, treatment delays, and

negative impact on quality of life and prognosis which was clearly impinged by (Oncology Nursing Forum 2012; Mohammad Ali Sheikhi et al. 2015).

Small brent et al (2010) conducted a study on Massage Modalities and Symptoms Reported by Cancer children were assessed in relation to massage. Twenty-two studies are discussed. Most studies were on Swedish massage, added by aromatherapy massage, foot reflexology, and acupressure. Symptoms assessed as outcomes included pain, fatigue, anxiety, nausea, and depression. Miranda L.Ayers., Olateju F. Olowe., (2015) also added certain other nursing interventions such as yoga, ginger, concord grape, music therapy, distraction , and other techniques yet the findings of the studies reviewed were mixed and varied as a function of several study characteristics. The most consistent symptom reduction was for anxiety and greater control of nausea and vomiting enhancing self efficacy.

A volume of evidence (Springer Verlag 2010; R K Wong et al. 2011;Hockenberry et al. 2012; Hughes D, Ladas E, Rooney D, Kelly K.2015) assessed on Children Coping Strategies for CINV to identify anticipatory, acute, and delayed CINV frequency and coping strategies used among pediatric patients with cancer. Convenience sampling was done and their tool being the Adapted Rhodes Index of Nausea and Vomiting for Pediatrics and the Kidcope Younger Version. The most preferred coping strategies were distraction and wishful thinking, whereas statistically the most effective strategy concluded was Swedish massage as a comforting measure.

Numerous studies (Luís Manuel Cunha Batalha 2010; Sarah G. Buttle 2011; Bilhut et al.2011;Rapaport et al.2012; Helen Cooke, Helen Seers 2013;**)** conducted a study to determine effectiveness of a single session of Swedish massage on neuroendocrine and immune function. The intervention tested was 45 minutes of Swedish Massage Therapy versus a light touch control condition, using highly specified and identical protocols. Swedish massage caused a positive effect in the immunological status. Despite having contributed to decrease pain the massage protocol was effective in

decreasing the interference of nausea and vomiting intensity always decreased after each massage session ($p<0.01$).

Multiple studies **(**Seyedreza Mazlum et al.2011; Lee et al 2011 Kutner et al. 2013; Mohammad Ali Sheikhi et al.2015) were conducted as a randomized controlled clinical trials within 4-18 years children under chemotherapy, who were divided into two (massage therapy and control) groups randomly. In the massage group at 0.5 hour and 24 hours before and 24 hours after chemotherapy, the patients were massaged (Swedish massage) for 20 minutes, respectively. The Mann–Whitney and chi-square tests reveal that in the massage group, the incidence ,severity, length, and times of nausea and vomiting were lower than those of the control group ($p< 0.05$), respectively. These studies concluded Massage therapy reduced CINV and recommended the nurses to practice in providing holistic care to the children.

In clinical setting, the investigator developed rapport with the children with cancer receiving chemotherapy, revealed that school age children had experienced CINV in course of their treatment in spite of antiemetic drugs; they experienced degeneration of self care and functional ability, in order to help the children to relieve from distressing effects and improving the quality of life. After thorough literature review and seeking experts opinion the investigator understood the physiology of CINV, identified a suitable tool to assess CINV and underwent training on Swedish massage as a nursing intervention to decrease the level of CINV and prevent further complications and long term consequences among school age children which is within the scope of nursing practice and integral to process of nursing care.

Hence the investigator took this topic as a research project in order to assess the effectiveness of Swedish massage on level of CINV among children with cancer and to develop standard nursing care therapy based on the outcome.

1.3 STATEMENT OF THE PROBLEM

A quasi experimental study to assess the effectiveness of Swedish massage on level of Chemotherapy Induced Nausea and Vomiting (CINV) among children with cancer at selected Hospital, Surat.

1.4 OBJECTIVES

1. To assess and compare the post test level of Chemotherapy Induced Nausea and Vomiting among children with cancer in study and control group.
2. To correlate the post test mean score of Chemotherapy Induced Nausea with Chemotherapy Induced Vomiting among children with cancer in study and control group.
3. To associate the selected demographic variables with the post test mean score of Chemotherapy Induced Nausea and Vomiting among children with cancer in study and control group.

1.5 OPERATIONAL DEFINITIONS

1.5.1 Effectiveness

Refers to the outcome of Swedish massage on level of Chemotherapy Induced Nausea and Vomiting among children with cancer receiving chemotherapy which was assessed 24 hours after each day's intervention for 3 days by using Modified Rhodes Index of Nausea and Vomiting.

1.5.2 Swedish massage

Refers to the gentle strokes performed by the investigator for 20 minutes to the children by placing them in prone position on a firm surface, then the investigator uses her pre warmed palm to start the strokes from the lower back up to the shoulder by using 5 main strokes (i.e.,) effleurage, pettrisage, tapotment, friction, vibration for a period of 4 minutes each under aseptic technique.

1.5.3 Chemotherapy Induced Nausea Vomiting

Refers to a common side effect experienced by the children before (anticipatory), during (acute) and after (delayed) receiving chemotherapy characterized by the urge to vomit followed by ejecting the contents of stomach through mouth.

1.5.4 Children with Cancer

Refers to those within the age group of 6-12yrs receiving chemotherapy in any cycle with at least four days of hospitalization for chemotherapy.

1.6 ASSUMPTION

Swedish massage may have an effect on level of CINV among children with cancer receiving chemotherapy.

1.7 NULL HYPOTHESES

NH_1- There is no significant difference between the post test level of Chemotherapy Induced Nausea and Vomiting among children with cancer in study and control group at $p < 0.05$ level.

NH_2- There is no significant correlation of post test mean score of Chemotherapy Induced Nausea with Chemotherapy Induced Vomiting among children with cancer in study and control group at $p < 0.05$ level.

NH_3- There is no significant association of the selected demographic variables with the post test mean score of Chemotherapy Induced Nausea and Vomiting among children with cancer in study and control group at $p<0.05$ level.

1.8 DELIMITATION

The study was delimited to a period of four weeks of data collection.

1.9 CONCEPTUAL FRAMEWORK

Conceptual framework is made of concepts and propositions that state the relationship between the concepts relevant to the study. Conceptual framework provides a foundation to foresee the occurrence of phenomena. It helps the nurse investigator to proceed with the research in an organized and orderly process by generating ideas for research.

Katharine Arnold (Kolcoba) born in 1944, graduated with RN., MSN., from Frances Payne Bolton School of Nursing in 1987 and began teaching at the university of Akron College of Nursing in 1987. Kolcoba's Theory of comfort was first developed in the 1900's. In 2010 she published an article; comfort theory to pediatrics, explaining the present approach to pediatrics as attempting to relieve discomfort and to gain potential utility of implementing this theory within an institution. It is a middle range theory for health in nursing practice, education and research. This theory has the stamina to place comfort in the forefront of healthcare. According to the model, comfort is a positive concept and is associated with activities that nurture and strengthen patients from an immediate desirable outcome of nursing care.

The conceptual framework adopted for this study was based on modified Kolcoba's theory of comfort. The theorist Katharine Kolcoba states that the patients may have various level of discomfort arising from various health changes and she identified that appropriate identification of the health care needs, intervening variables and comforting interventions (relief, ease and transcendence) would promote enhanced comfort over a period of time that helped the individual to achieve the health seeking behavior that ultimately lead to framing of best practices and best policies at the health care institutions. The present study was aimed to reduce the level of CINV among children with cancer. The theorist states that best practices leads to better quality of life. It has 5 components a) Health care needs of children b) Comforting interventions c) Enhanced comfort d) Health seeking behavior e) Institutional integrity.

- **Health care needs of the children**

The theorist defines health care needs as those needs identified by the children and or the family in a particular nursing practice setting. In this study the investigator identified CINV are the major side effects of the children with cancer receiving chemotherapy hence the investigator collected the demographic variables as the baseline data.

- **Comforting interventions**

According to this theory, comforting measures refers to the nursing interventions that are designed to address the specified health care need based on relief, ease and

transcendence. Relief is the specific need of the patient; in this study the investigator selected specific need as children with cancer experiencing CINV. Ease is the comfort experienced by the person; in this study the investigator used Swedish massage along with Hospital routine (antiemetic drugs) as ease for the study group and only Hospital routine for the control group. Transcendence is the end result experienced by the individual; here the investigator conducted the post test for the children with cancer by using Modified Rhodes Index of Nausea and Vomiting.

- **Enhanced comfort**

According to the comfort theory, the enhanced comfort is the desirable outcome of the nursing care accomplished by relief, ease and transcendence over a period of time. In this study, the investigator assessed the effectiveness of Swedish massage 30 minutes prior to chemotherapy, 24 and 48 hours after chemotherapy for a period of 3 consecutive days by using Modified Rhodes Index of Nausea and Vomiting.

→ **Reinforcement-** If there was reduction in the level of CINV after providing Swedish massage along with Hospital routine in the study group, the investigator recommended for the reinforcement of the intervention.

→ **Enhancement-** If there was no reduction in the level of CINV after providing Swedish massage along with Hospital routine in the study group and only Hospital routine in the control group, reassessment was done and training was given to the caregivers to enhance the intervention thereby comforting the child.

- **Health seeking behavior**

According to this theory, health seeking behavior is the effect of enhanced comfort on the individual. In this study the investigator, assessed the health seeking behavior in study and control group by deriving positive (Reduction in level of CINV) and negative outcome (No reduction in level of CINV).

- **Institutional integrity**

Institutional integrity includes the best practices and best policies which the institution frames as procedures and protocols for the overall use after collecting the evidences. In this study the investigator reported the findings of the study to the Medical Director of Anand Hospital, Surat. He appreciated the investigators efforts in deriving a solution to this distressing effect of CINV and recommended training to the staff nurses to follow Swedish massage as routine practice and he also advised the staff nurses to train the caregivers of children with cancer.

Thus, the Kolcoba's Theory of Comfort for children with cancer provided to be perfect guidance for the logical framework development of the study which enhanced the investigator to design the outline for this study by giving related phenomena and concepts for children with cancer undergoing chemotherapy. It also helped the investigator to blend various components of the theory into different aspects of nursing practice throughout the study, thus enabling to identify the effectiveness of Swedish massage on level of CINV among children with cancer.

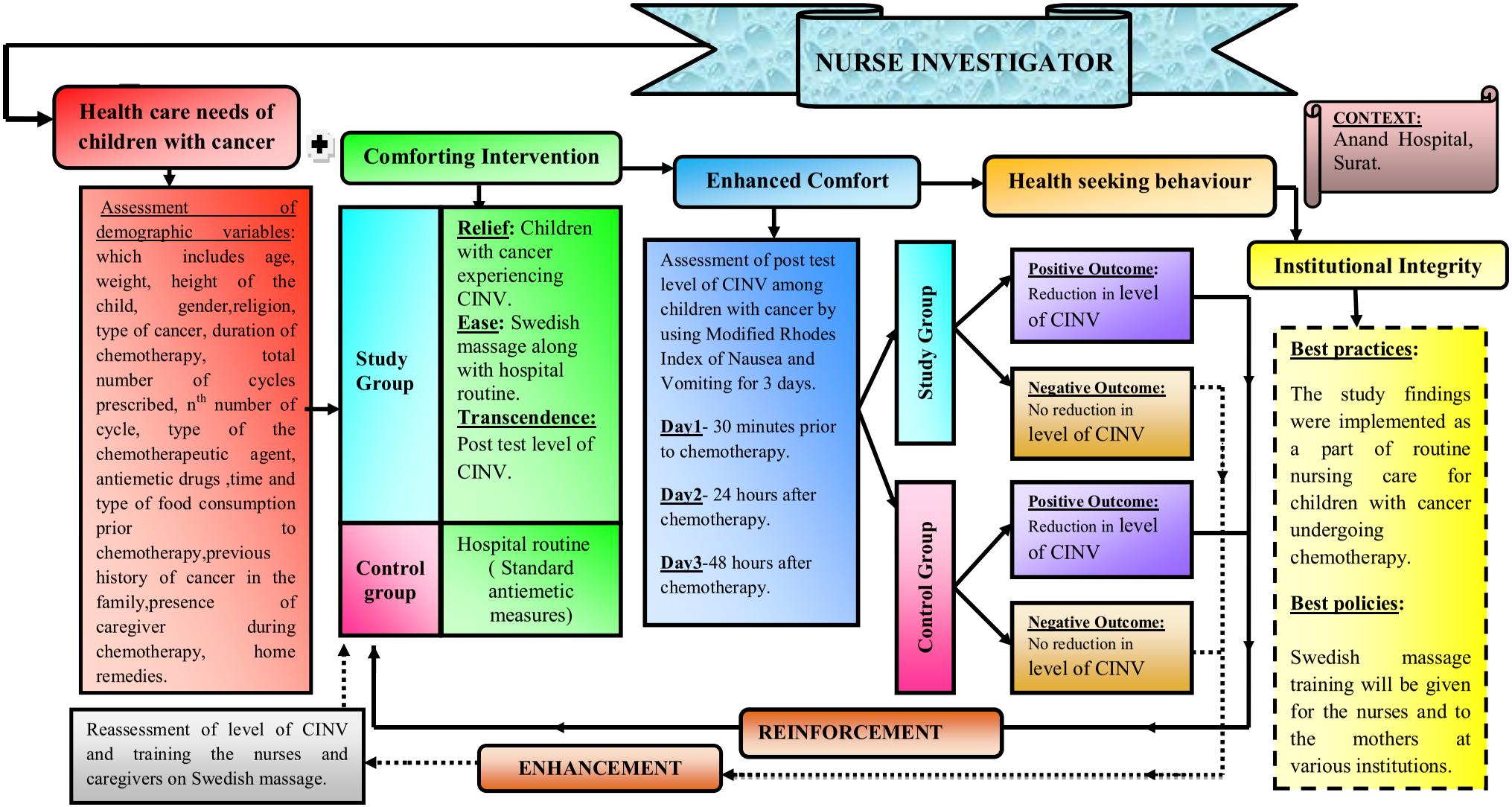

Figure1.9.1 CONCEPTUAL FRAMEWORK BASED ON KOLCABA'S THEORY OF COMFORT

1.10 OUTLINE OF THE REPORT

CHAPTER1: Dealt with the background of the study, need for the study, and statement of the problem, objectives, operational definitions, null hypothesis, assumptions, delimitations, conceptual framework**.**

CHAPTER2: Focuses on review of literature related to the present study**.**

CHAPTER3: Enumerates the methodology of the study.

CHAPTER4: Presents data analysis and data interpretation.

CHAPTER5: Deals with the discussion of the study.

CHAPTER6: Gives the summary, conclusion, implications and limitations of the study.

The study ends with selected references and appendices.

CHAPTER – 2

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Review of literature is a systematic search of a published work to gain information about a research topic. **(Polit and Hungler, 2012).**

The literature review is based on extensive survey of books, journals and international nursing studies. A review of literature relevant to the study was undertaken which helped the investigator to develop insight into the problem and gained information on the solution in the past, present and expected future. The investigator comprehended the concepts well and laid down a broad foundation for the study intervention, tool and the conceptual framework framed based on Kolcoba‘s theory of comfort to proceed with the study.

The review of literature was done using the key words such as children with cancer, childhood cancer, level of CINV, CIN, CIV, side effects of chemotherapy, Swedish massage, therapeutic massage, standard antiemetic drugs, pediatric cancer statistics, and non pharmacological interventions for children with cancer. These reviews were searched based on electronic and standard databases such as Cochrane library, Medical Literature Analysis and Retrieval System Online (MEDLINE), Cumulative Index to Nursing & Allied Health (CINAHL), Elton B. Stephens Co.(EBSCO), Pub Med, Google scholar, National Cancer Data Base**,** Excerpta Medica data BASE (EMBASE), British Nursing Index, Psych INFO, Allied and Complementary Medicine Database (AMED), System for online Grey Literature in Europe (SIGLE), CancerLit and other unpublished studies from dissertations. It includes randomized clinical trials, quasi experimental, double blind studies, cross sectional and longitudinal trials, uncontrolled observational studies, cohort studies and crossover studies and systematic reviews. The reviews were taken within or close to the last five years which ensured that the studies reflect the recent and relevant to advances in technology, disease, and practice.

The aim of this review was to examine the literature on Swedish massage given to children with cancer and identify relevant outcomes associated with reduction in the level of CINV.The intention was to gather evidence to achieve better understanding of the topic and its impact, deriving improved nursing measures to improve the quality of life among children with cancer.

For the purpose of logical and systematic sequence the chapter is divided into the following two sections:

Section 2.1: Scientific reviews related to level of CINV among children with cancer.

Section 2.2: Scientific reviews related to Swedish massage among children with cancer.

SECTION 2.1: SCIENTIFIC REVIEWS RELATED TO LEVEL OF CINV AMONG CHILDREN WITH CANCER.

- **CINV and its impact among children with cancer**

A huge number of researchers (Choi MR, Jiles C, Seibel NL, 2010; Jordan K, Rolia F, Molassiotis A, Maranzano E, Clark-Snow RA, Feyer, 2010; P .Steven M. Grunberg, 2010; Navari et al, 2011; Basch et al, 2011; Mohammad Ali Sheikhi et al, 2015) quoted that chemotherapeutic regimens have improved and are more finely targeted than in the past, but CINV remains a major obstacle and affects children satisfaction with treatment. Despite the development of effective antiemetic drugs and standardized guidelines recommending their use, clinical practice still lags behind. Children fall into the pit of undertreated when taking moderately or highly emetogenic chemotherapy while, perhaps, being over treated when receiving mildly emetogenic chemotherapy.

Multiple studies (BC Cancer Agency 2011; Karin Jordan et al 2011; Geiger and Wolfgram Trials 2013; Ayers, Miranda L. and Olowe, Olateju F 2015) view that inadequate relief of CINV becomes a very distinct problem as it may delay or even hasten potentially life-saving conventional treatment interventions. Poorly managed CINV can give rise to medical complications such as poor nutrition, dehydration, electrolyte imbalances, and physical and mental deterioration. In such instances it requires the use of rescue medication and possible emergency department visits which results in extravagant costs. Few researchers add on to this that around 70-80% of children receiving chemotherapy are at risk of CINV, which may interfere with their food pattern and the ability to perform activities of daily living (Vidall et al 2011). As a result, weight loss, susceptibility to infections, malnutrition and metabolic imbalances, such as hyponatremia, hypokalemia, and metabolic acidosis may occur. (Taspinar & Sirin, 2010).

Numerous studies (Mark G. Kris, MD et al 2010; Yeh CH et al 2011; Rebecca Hawkins et al 2014; Kang HJ et al 2015; Hesketh PJ et al 2015) have identified that chemotherapeutic drugs can cause nausea and vomiting by several mechanisms. They act as irritants to the stomach and duodenum's mucosal lining, which stimulates certain nerves that activate the vomiting center and the chemoreceptor trigger zone (CTZ) in the brain which cause vomiting. They can also activate the CTZ by causing intestinal obstruction, delayed gastric emptying, or inflammation. Therefore, CINV involves coordination of several organs of the gastrointestinal tract, the peripheral and central nervous systems despite these improvements in comprehending its pathophysiology; CINV continues to affect a large number of cancer children. Clinical Advances in Hematology and Oncology (2011) conveys that CINV significantly affects their ability to complete household tasks, enjoy food, spend time with loved ones, and perform daily

function and recreation. Although it is not necessarily the most dangerous treatment related adverse event, CINV causes a major disruption to a patient's lifestyle, severely limiting his or her ability to participate in social functions thereby hampering their ability to enjoy their childhood. Thus, healthcare team members who care for cancer children have a critical role in the prevention and management of CINV, and it is incumbent upon them to ensure that all the children treated with chemotherapy are treated appropriately according to current evidence based practice guidelines.

- **Assessment of CINV among children with cancer**

Sarah. G Brearley (2011) elegantly explains that there is a continuing need to detect CINV and to develop clinically useful assessment tools. The systematic assessment of symptoms had proved to be associated with reduced symptoms of distress overtime. A wide variety of tools and methods to assess nausea and vomiting exist, chief among these are behavioral measures such as observer ratings, physiological measures and self reported tools. With symptom research in general, patient reporting is considered to be the gold standard and is a favored method of measuring the subjective and unobservable experience of nausea. There are many self assessment tools including daily diaries, logs and journals, visual analogue scales (VAS), ordinal scales and multidimensional scales.

Baxter et al (2011) A pictorial nausea scale with 6 faces ranging from 0-10, the Baxter Retching Faces (BARF) scale was developed in 3 stages. Children were presented with VAS for nausea and pain, the pictorial Faces Pain Scale and the BARF scale. American Academy of Pediatrics described the development of BARF scale with evidence of construct validity for a self-report assessment of the severity of pediatric nausea. The scale had convergent and discriminant validity, along with an ability to detect change after treatment.

A Visual Analogue Scale; a brief nausea index used by Post-White et al (2011); which was a modification of the Brief Pain Inventory; the Rhodes Inventory of Nausea, Vomiting, and Retching, a chemotherapy problem checklist was used by Dibble et al (2011); this was a modification of the Chemotherapy Knowledge Questionnaire with a daily log of nausea and The Functional Living Index-Emesis (FLIE) questionnaire by Clinical Advances in Hematology and Oncology (2011). CINE QOL- Chemotherapy Induced Nausea and Emesis Quality of Life American cancer society 2013; Osoba nausea and vomiting quality of life, CINV symptom tracker- Eiasai (2013); Halpin, A, Huckabay, L., Kozuki, J. Forsythe, D. (2010). Weigh the benefits of using a 0-to-5 scale. Amy L et al (2013).

The Rhodes Index of Nausea, Vomiting and Retching (RINVR) is a patient self-report tool to assess the objective and subjective factors of nausea and vomiting. Cronbach's alpha of nausea, vomiting, retching and total experience scores of the RINVR of all items were strongly correlated Coefficients of construct validity for nausea components and emetic components of the RINVR at $p < 0.0001$.The overall incidences of nausea and vomiting were assessed and the number of children "great" total experience category was 1.33% or less. There was no significant difference of VAS for nausea between "severe" and "great" nausea experience categories and therefore concluded that RINVR was a valid and reliable tool to assess post operative nausea and vomiting by Korean J Anesthesiol (2007).

Janelle M. Wood et al (2011) comprehensive critique of instruments is important for nurses attempting to select a tool to guide optimum care for patients in the clinical setting. Adapted Symptom Distress Scale (ASDS); Common Toxicity Criteria (CTC); Organization for Research and Treatment of Cancer (ORTC); Edmonton Symptom Assessment Scale (ESAS); Functional Assessment of Cancer Therapy General(FACT-G); Functional Living Index Cancer (FLIC); Functional Living Index Emesis (FLIE); Morrow Assessment of Nausea and Emesis(MANE); Multinational Association of Supportive Care in Cancer (MASCC); Antiemesis Tool (MAT); MD Anderson Symptom Inventory Core Items; Memorial Symptom Assessment Scale (MDASI); National Cancer Institute (NCI); Nausea Rating Index (NRI); Numerical Rating Scale (NRS);Nausea, Vomiting, and Retching (N/V/R); Overall Nausea Index (ONI); Visual Analog Scale (VAS);Verbal Categorical Scale (VCS). This review indicates that the tools available vary in the comprehensiveness of their assessment of all 3 symptoms, with retching being included least often and in less detail. Four aspects of nausea were assessed being its duration, frequency, severity, and associated distress. Because of the subjective nature of the experience, nausea may be the most difficult symptom for care providers to measure. However, ample research has shown that it has an indepth negative impact on quality of life than vomiting. Questions related specifically to vomiting evaluated 5 components being its duration, frequency, volume, severity, and distress and ultimately concluded that only the tools developed by Rhodes provided a separate assessment of all 3 symptoms.

The review highlighted the strength and weakness of current tools. The multiple domains, phases and aspects of CINV signify that the assessment tools varied markedly. The diverse requirements of research and clinicians also contribute to variations. There was notable disparity in quality of scales and paucity in terms of their development and psychometric evaluation. It was evidenced that several self assessment scales currently viewed as well validated tools have problems in terms of their validity, reliability and appropriateness.

SECTION 2.2: SCIENTIFIC REVIEWS RELATED TO SWEDISH MASSAGE AMONG CHILDREN WITH CANCER.

- **Swedish massage**

Sara L. Ackerman et al (2012) remarked that more recently, a growing body of scientific literature on Swedish massage bolstered by its widespread popular use has led to the reintroduction of various forms of massage as an adjunct to biomedical therapies. In addition, the particular strength of the massage intervention appeared to be in promoting pleasurable sensations and a mood of relaxation, with most of the children dozing off near the end of massage sessions, relief from symptoms such as pain , nausea , vomiting, inflammation, positive feeling, relaxation, sleep, heightened sense of control, intimacy and bonding, improved parents confidence as caregivers.

Swedish massage can provide nurturing touch in environments where painful touch is often medically necessary. Swedish massage addresses the holistic concerns of the pediatric clients -physical, psychological, emotional and spiritual .Massage benefits for cancer children are decreased pain, anxiety and fear, improved relaxation, leukocytosis and increased production of neutrophils, endorphins (natural painkillers), enhanced immune function, decreased depression, decreased production of stress hormones (cortisol) as highlighted by Tina Allen (2011).

Certain researchers (Knorring et al 2011; R. K Wong et al 2011) contribute that Swedish massage involves the administration of combinations of specific physical manipulations applied in a systematic way, with varying rate, and rhythm, duration, intensity and direction to the soft tissues of the body using specific manual techniques such as *effleurage, petrissage, tapotement, friction, vibration.* Helen Cooke, Helen Seers(2013) added that children who were massaged showed decreased levels of stress hormones and children who were experiencing conditions such as rheumatoid arthritis, asthma or diabetes report decreased anxiety and show feelings of increased well being after massage. Swedish massage is used to help children suffering from chronic pain, ADHD, autism and other special needs also benefit greatly from the massage experience.

Few researchers (Rosen et al 2013; Helen Cooke, Helen Seers 2013) conducted a randomized controlled pilot studies to assess the use of massage therapy to reduce pain and anxiety in children with cancer who were undergoing a minor surgical procedure. The control group received structured attention. The group who received massage therapy reported a significant reduction in anxiety, but the difference between treatment groups for pain levels was not significant. A further randomized pilot study Lee MS, Lee EN; Ernst E (2011) determined the feasibility and effects of Swedish massage given at home for clients with metastatic cancer. Participants were randomized to one of three

interventions; massage therapy, a usual care control and a no-touch control. Although there was a trend towards improvement in pain and sleep, no significant changes were found in the primary outcomes pain, anxiety and alertness. Significant enrichment in quality of life was found among the secondary outcomes.

Mostly studies on Swedish massage have measured predefined patient outcomes, usually medical and psychological factors. Available evidences are sufficient to indicate that Swedish massage is a useful discipline for the relief of a variety of symptoms that affect both the body and the mind. Mechanistic studies are required to understand the psycho physiologic effects of Swedish massage and the influence of those effects on daily clinical practice.

- **Effectiveness of Swedish massage on the level of CINV**

Massage therapy is currently being offered to patients at several major cancer centers around the United States and in many other countries around the world. The available data indicated that there are potential benefits to patients from receiving massage properly adapted to cancer and its treatment.

A couple of studies (Small Brent et al 2010; Oncology Nursing Forum 2012; Mohammad Ali Sheikhi et al 2015;Miranda L. Ayers and Olateju F. Olowe 2015) reported that moderately massaging children back led to relaxation, emotional health, appetite improvement, and nausea reduction in cancer patients receiving chemotherapy. It was shown that Swedish massage in cancer patients under chemotherapy decreases nausea and vomiting to 45% as compared to control group. Based on these results, they suggested that nurses can effectively apply massage to alleviate pain, nausea and vomiting in patients with cancer and accordingly, patients and their families have to be trained in this regard.

Few researchers (Myers et al 2010; Cassileth et al 2012) studied on narrative review about massage modalities and symptoms reported by cancer patients discussed on 22 studies and most studies were on Swedish massage, preceded by aromatherapy massage, foot reflexology, and acupressure. Symptoms assessed as outcomes included pain, fatigue, anxiety, depression, mostly nausea and vomiting. Plenty of other researchers (Luis Manuel Cunha Batalha 2010; Dewan, Singhal, & Harit, 2010; Hockenberry et al 2012; Vashani et al 2013) also added that the most consistent symptom reduction was anxiety, greater control on reduction of nausea and vomiting too, proving that Swedish massage facilitate circulation, reduce excess muscle tension, increase flexibility, and promote relaxation. Therefore these researchers viewed Swedish massage as a non-invasive, inexpensive, comforting, and free of side effects and greatly appreciated by recipients.

A recent study in the International Journal of Therapeutic Massage & Bodywork (IJTMB), researchers Jolie N. Haun, John Graham-Pole, and Brendan Shortley (2013) conducted a study on thirty children with cancer and blood disease, ages 6 months to 17 years old. The treatment group received 20-minute sessions of Swedish massage once a day for 4 days for inpatients or once a week for approximately 4 weeks for outpatients and no massage for the control group. Results confirmed that the treatment group showed significant reduction in nausea and vomiting which brought about an improvement both physically and psychologically.

Multiple studies (Luis Manuel Cunha Batalha 2010;Williams.A 2010; Sarah G. Buttle 2011 ;Bilhut et al 2011;Rapaport et al 2012; Helen Cooke, Helen Seers 2013; Mohammad Ali Sheikhi et al 2015 **)** conducted studies to determine effects of a single session of Swedish massage on neuroendocrine and immune function and other possible actions which identified that it started of with local biochemical changes locally innervating the sympathetic and parasympathetic nervous system releasing various hormones and neurotransmitters enhancing the immune function, evoking a relaxed response and decrease stimuli to chemoreceptor trigger zone. Henceforth, proving Swedish massage a beneficial nursing intervention by exploring the scientific significance behind it.

The above scientific reviews related to Swedish massage conclude that it is highly beneficial to children experiencing extremely unpleasant CINV by reducing its internal and external extravagant costs .It remarkably has significant impact on the physical, psychological aspects of these children quality of life and functional ability. It enriches the parent's involvement by teaching them and performing it to their children nevertheless even improving pediatric client satisfaction.

- **Other pharmacological and non pharmacological interventions to reduce the level of CINV among children with cancer.**

Huge number of researchers (Gary. H Lymann 2011; Rudolph M. Navari 2012; Cancer Care Nova Scotia and Sarah Payne and David Miles 2014) suggest that the management of CINV includes treatment strategies for both acute (within 24 hours of chemotherapy administration) and delayed (>24 hours after chemotherapy) emesis. Effective management of acute and delayed nausea and vomiting is crucial to prevent anticipatory nausea and vomiting. In addition to pharmacologic antiemetic agents, other drugs such as benzodiazepines and non-pharmacologic methods can modify the patient experience and reduce morbidity and anxiety from nausea and vomiting experiences.

Practice guidelines are intended to assist health care professionals with decisions throughout the spectrum of the cancer experience.

Many enthusiastic updation committees (American society of clinical oncology 2011; Basch et al 2011) noted the importance of continued symptom monitoring throughout therapy and accurate drug calculations based on the children body surface area. Clinicians underestimate the incidence of nausea, which is not as well controlled as emesis. Combined anthracycline and cyclophosphamide regimens were reclassified as highly emetic. Children who receive this combination or any highly emetic agents should receive a 5-HT3 receptor antagonist, dexamethasone, and a NeuroKinin 1 (NK1) receptor antagonist. Preferential use of palonosetron is recommended for moderate emetic risk regimens, combined with dexamethasone. For low-risk agents, children can be offered dexamethasone before the first dose of chemotherapy.

Miranda L.Ayers., Olateju F. Olowe., (2015) conducted a systematic review on the use of yoga, acupressure, ginger, music therapy concord grape, distraction and other techniques concluded that they had greater control and enhanced self efficacy. Two research studies have examined the effect of yoga on CINV (Raghavendra et al 2010; Usharani et al 2012) subjects were randomly allocated to receive yoga and other supportive therapy intervention during the course of their chemotherapy. Intervention consisted of both supervised and home practices while the control group received coping preparation and supportive therapy during their Hospital visits over a complete course of chemotherapy. There was a significant decrease in post test level of CIN frequency and intensity and intensity of anticipatory nausea and vomiting. However, these studies only showed the impact of yoga on specific type of cancers.

Numerous studies (Dibble et al 2010; Taspinar and Sirin 2010; Suh 2012; Genc and Tan 2014) identified the effects of acupressure and nurse-patient counseling along with other antiemetic drugs found a significantly reduced level of CIN between the experiment and control groups. However, CIV was only reduced in the groups who participated in acupressure. They found that a combination of both acupressure and nurse-patient counseling resulted in the lowest number of CINV episodes, with the highest reduction in nausea from acupressure. Although there was a decrease in vomiting related to the use of acupressure, patients in the study recorded incorporating a wide variety of their own non-pharmacological interventions of their own including exercise, diet modification, fresh air, visualization, diet modification, peppermint tea, ginger tea, a spoonful of honey, avoiding smells, aromatherapy, avoiding stress and even prayer.

Most of the studies reported mixed findings about the effect of other non-pharmacological interventions on CINV. These interventions include the use of music and visual therapy Karagozoglu, Tekyasar, and Yilmaz (2013), social support and distraction Rodgers et al (2012), grape juice flavonoids Ingersoll et al (2010). Rodgers et al (2012) used a cohort design to study the effects of coping strategies in forty children with cancer, age seven to twelve years. They revealed that social support and distraction were the most effective strategies for coping with CINV.

Few studies (Genc, Can, and Aydiner 2013; Molassiotis et al 2013) in the United Kingdom, provided evidence that the encouraging signals through wrist band in relation to improved nausea experience. Many researchers have studied CINV and ginger which is grown in many parts of the world and therefore is a cost effective plant. Multitude of studies (Pillai et al 2011; Bakhshi, 2011; C. Kasper and B. Pierce 2011;Alparslan et al 2012 ; Ryan et al 2012 ;Panahi et al 2013) revealed that the intervention groups were given 800 mg ginger tablets twice a day for four months while the control group were given only antiemetic drugs. The intervention group reported no occurrence of nausea and vomiting and 75% of the control group reported nausea or vomiting on an average. On the other hand, Zick et al (2013) used a randomized double blind placebo trial to compare the effect of a low-dose (1.0g) and a high-dose (2.0g) powdered ginger root extract versus placebo on reducing the prevalence and severity of delayed nausea and vomiting proving no significant effect on CINV between the groups.

Summary:

The above literatures were selected to provide high quality of holistic nursing care to the children with cancer with the scientific body of knowledge adhering to the facts and figures pertaining to today's world. During the search process the investigator found many flaws and gaps in the literatures as they dealt mostly with the impact of reduction in level of CINV with a combination of non pharmacological approaches as most of the studies being narrative reviews and Meta analysis. The effectiveness of Swedish massage was investigated but hardly few in the context of children with cancer. In order to bridge the gap the investigator conducted a study to assess the effectiveness of Swedish massage on the level of CINV among children with cancer. During this process the investigator faced difficulty in gathering Indian related literatures pertaining to topics such as Swedish massage and tools to assess CINV but overwhelmed with the fact that most of them were nursing studies.

CHAPTER – 3

RESEARCH METHODOLOGY

RESEARCH METHODOLOGY

This chapter describes the methodology adopted in this study to assess the effectiveness of Swedish massage on level of Chemotherapy Induced Nausea Vomiting (CINV) among children with cancer at selected setting, Surat.

This phase of the study deals with the research designs, variables, setting of the study, population, sample, criteria for sample selection, sample size, sampling technique, development and description of the tool, content validity, reliability of the tool, pilot study, procedure for data collection and plan for data analysis.

3.1 RESEARCH APPROACH

Quantitative research approach.

3.2 RESEARCH DESIGN

The research design adopted for this study was quasi experimental post- test only research design. According to **Polit and Beck (2012),** the quasi experimental research design had an element of manipulation but lack at least one of the two properties that characterize true experimental study: randomization or control. The quasi experimental designs are generally used to establish the causality (effect of independent variable on dependant variable).

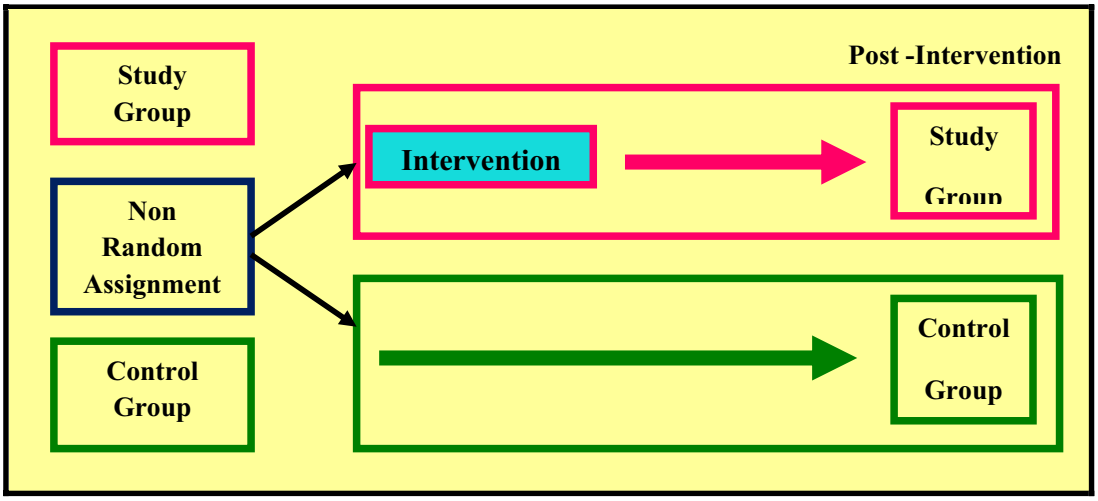

Fig 3.1: Research Approach- Quasi experimental post test only design

In this study the investigator had adopted post test only research design since the level of Chemotherapy Induced Nausea and Vomiting can be assessed only after administration of Swedish massage. The investigator conducted this study with a control group in order to show its effectiveness but could not randomize due to non availability of samples. This made the investigator to undertake quasi experimental post test only design for this study.

→ **Manipulation**- The investigator performed Swedish massage by using gentle strokes for 20 minutes to the children by placing them in prone position on a firm surface, then the investigator uses her pre warmed palm to start the strokes from the lower back up to the shoulder by using 5 main strokes (i.e.,) effleurage, pettrisage, tapotment, friction, vibration for a period of 4 minutes each under aseptic technique.

→ **Control –** The investigator introduced control over the experimental situation; the investigator had a control group who followed the Hospital routine i.e., standard antiemetic measures.

The schematic representation of the quasi experimental study is as follows:

<table>
<tr><th>Group</th><th>Intervention (×)</th><th>Post Test(o_1), (o_2), (o_3) (24 hrs after intervention for 3 consecutive days)</th></tr>
<tr><td>Study Group</td><td>The investigator performs gentle strokes on the children with cancer receiving chemotherapy by placing them in prone position on a firm surface, then the investigator uses her pre warmed palm to start the strokes from the lower back up to the shoulder by using 5 main strokes (i.e.,) effleurage, pettrisage, tapotment, friction and vibration for a period of 20 minutes under aseptic technique which was given as follows:
Day-1= 24 hours before chemotherapy.
Day-2= 30 minutes prior to chemotherapy.
Day-3= 24 hours after chemotherapy.
Along with Hospital Routine (Standard antiemetic measures) to assess the anticipatory, acute and delayed level of CINV.</td><td rowspan="2">Assessment of post test level of CINV among children with cancer receiving chemotherapy by using Modified Rhodes Index of Nausea and Vomiting.</td></tr>
<tr><td>Control Group</td><td>(HOSPITAL ROUTINE)
Standard antiemetic measures</td></tr>
</table>

3.3 VARIABLES

3.3.1 Independent Variable

The independent variable for the present study was Swedish massage.

3.3.2 Dependent Variable

The dependent variable for the present study was level of Chemotherapy Induced Nausea and Vomiting.

3.3.3 Extraneous Variables

It consisted of age in years, weight in kgs, height in cms, gender, religion, type of cancer, duration of chemotherapy, total number of cycles prescribed, n^{th} number of cycle, type of the chemotherapeutic agent, antiemetic drugs, time of food consumption prior to chemotherapy, type of food consumed by the child prior to chemotherapy, previous history of cancer in the family, presence of caregiver during chemotherapy and home remedies.

3.4 SETTING OF THE STUDY

The study was conducted in Anand Hospital, Surat. It is a 250 bedded private Hospital exclusively for pediatric services. It has a 20 bedded chemotherapy ward. There were around 15-20 children diagnosed per week with cancer receiving chemotherapy. The Hospital also provides accommodation facilities nearby for children receiving chemotherapy.

3.5 POPULATION

3.5.1 Target Population

All children with cancer between 6-12yrs receiving chemotherapy in chemotherapy ward.

3.5.2 Accessible Population

All children with cancer between 6-12 yrs receiving chemotherapy, who were admitted in chemotherapy ward at Anand Hospital, Surat.

3.6 SAMPLE

Children with cancer between 6-12 years receiving chemotherapy in chemotherapy ward at Anand Hospital was selected for both study and control group.

3.7 SAMPLE SIZE

The Sample size consisted of minimum 60 children with cancer (30 were in study and 30 in control group) receiving chemotherapy who fulfilled the inclusive criteria.

3.8 SAMPLING TECHNIQUE

Non Probability Purposive Sampling technique was used for the selection of the samples for the study as the investigator found it difficult to randomize the sample in chemotherapy ward.

3.9 CRITERIA FOR SAMPLE SELECTION

3.9.1 Inclusive Criteria

1. Children within the age group of 6-12 years receiving chemotherapy in any cycle with at least 4 days of Hospitalization.
2. Children with cancer receiving chemotherapy with interval of 2 days for next cycle of chemotherapy.
3. Children who are diagnosed with any type of blood cancer.

3.9.2 Exclusive Criteria

1. Children with associated co morbid illness.
2. Children diagnosed with critical illness.
3. Children who are not willing to participate.

3.10 DEVELOPMENT AND DESCRIPTION OF THE TOOL

After an extensive review of literature, discussion with the experts in the field of pediatrics and with the investigator personal experience**,** Modified Rhodes Index of Nausea and Vomiting was adapted as an apt tool for the study.

The tool constructed in this study has two parts:

3.10.1 Data collection tool: This consisted of 2 sections

Section A: Assessment of demographic variables

Section B: Modified Rhodes Index of Nausea and Vomiting.

3.10.2 Intervention Tool (Swedish massage**)**

3.10.1 DATA COLLECTION TOOL

Section A: **Assessment of Demographic Variables**

Structured interview schedule and medical record review was used to assess the demographic data. It consisted of demographic variables such as age in years, weight in kgs, height in cms, gender, religion, type of cancer, duration of chemotherapy, total number of cycles prescribed, n^{th} number of cycle, type of the chemotherapeutic agent, antiemetic drugs, time of food consumption prior to chemotherapy, type of food consumed by the child prior to chemotherapy, previous history of cancer in the family, presence of caregiver during chemotherapy and home remedies.

Section B: Modified Rhodes Index of Nausea and Vomiting

The tool Modified Rhodes Index of Nausea and Vomiting was developed by Korean J Anesthesiol is a patient or caregiver self-reported instrument to assess the objective and subjective factors of nausea and vomiting. The investigator explained the tool to the caregivers and obtained the subjective data from them then the investigator coded objectively. The tool has got 8 questions related Chemotherapy Induced Nausea and Chemotherapy Induced Vomiting and has been categorized as anticipatory, acute and delayed CINV. Thus this scale has been a great asset to the investigator to assess the CINV among children with cancer.

3.10.2 INTERVENTION (Swedish massage) It is a type of massage therapy referring to 5 gentle strokes applied from the lower back upto the shoulder of the children with cancer.

Time **:** 20 minutes

Method **:** One to one method

Venue **:** Treatment room

Pre preparation:

The investigator had given prior information to the parents and children that the intervention will be given to the child 24 hours and 30 minutes prior to chemotherapy and 24 hours after chemotherapy. The investigator obtained informed written consent from the parents/caregivers. The investigator then prepared a bed with clean linen in the treatment room to maintain privacy for the children. The investigator performed the massage with or without the presence of the parents according to the child's choice. The

investigator had performed hand hygiene and adorned face mask before handling the children following strict aseptic techniques.

During the procedure:

The child was asked to lie in prone position with their upper garment removed up to their waist and is covered with a bed sheet from the waist. After thorough hand washing the investigator began the procedure by applying mild pressure on the child's skin. Then the investigator initiated the procedure of Swedish massage by using her palm, stroked the child from the buttocks up to the shoulder and then moved downward to the buttocks using less pressure. Then the investigator used her thumb to oppose finger, knead and stroke the right half of the back with her right hand, knead and stroke the left half of the back with her left hand. Starting from buttocks moved towards the child's shoulder and then moved again down the back. The investigator used fleshy sides (proximal) of her hands lightly stroked the back from the buttocks up to the shoulder and repeated it again. Next, the investigator used the thumb pads or fingertips applied deep, circular movement near joints and other bony areas along the sides of the spine from the buttocks up to the spine of the child. Lastly, the investigator pressed the child on the back and upper limbs, ended by rapidly shaking.

The following steps are discussed in the table given below:

Technique	Steps	Duration	Physiology
Effleurage	Long gliding strokes from the base of the spine up to the shoulder.	4 minutes	Manipulation of muscles ↓ Modulate local blood flow, oxygen and lymph drainage. ↓ Influence neural activity (sub cortical nuclei) on CNS. ↔ Parasympathetic sympathetic nervous system. ↓ Innervates the GI tract ↓ Release endorphins, hormones, neurotransmitters. ↓ Reaches the limbic system, vomiting center and higher cortical centers of brain. ↓ Evoke relaxation response of muscles there by decrease stimuli to Chemoreceptor's trigger zone. ⇓ Reduction in level of CINV.
Petrissage	Gently lifting muscles away from bone, then rolling and squeezing them again with gentle pressure from the base of the spine up to the shoulder.	4 minutes	
Tapotment	Series of briskly applied percussive movements, using the hands alternately to strike or tap the muscles from the base of the spine up to the shoulder.	4 minutes	
Friction	Most penetrating of all the strokes, and consists of deep circular or transverse movements made with the thumb pads or fingertips. The therapist applies deep, circular movement near joints and other bony areas (the sides of the spine) from the base of the spine up to the shoulder.	4 minutes	
Vibration	Pressing hands on the back from the base of the spine up to the shoulder, and ends by rapidly shaking for a few seconds with mild pressure.	4 minutes	
Total		20 minutes	

Post Procedure (After care): The children were dressed and then allowed to perform their routine activities.

3.11 CONTENT VALIDITY

The content validity of the data collection tool was ascertained from the following field of expertise:

Chief pediatrician - 1

Pediatric oncologist - 1

Pediatric nursing specialist - 2

All the 4 experts had given their consensus, the additions and suggestions given by the experts were incorporated in the tool and the tool was finalized.

3.12 ETHICAL CONSIDERATION

The study was approved by the Ethical Committee of International Center for Collaborative Research (ICCR), Omayal Achi College of Nursing and the ethical principles were followed in the study.

(A) BENEFICENCE

- **Freedom from harm & discomfort**

Participants were not subjected to unnecessary risk for harm and discomfort during the study period. The participants were given full freedom to disclose their view in case of discomfort they feel during the study. A no harm certificate was obtained from the Hospital authorities along with which the investigator adorned personal protective equipment such as face mask and cap after strict hand washing to prevent cross infection to the children.

- **Protection from exploitation**

Parents of the children were assured that their participation or information they provided would not be used against them. The investigator completely explained the procedure and nature of the study to the caregivers and ensured that the participants in the study would not be exploited in any cost or denied from fair treatment.

(B) RESPECT FOR HUMAN DIGNITY

The investigator followed the second ethical principle of respect for human dignity. It includes the right to self-determination and the right to self -disclosure.

- **The Right to Self-determination**

The investigator had provided full freedom to the caretakers to decide voluntarily to participate in the study and in the intervention or to withdraw from the study and also that they had the right to ask questions at any time during the course of study.

- **The Right to Full Disclosure**

The investigator fully explained the nature of the study, the person's right to refuse or participate in the study. Written informed consent was obtained from all the caretakers and assent from children.

(C) JUSTICE

The investigator followed the third ethical principle of justice and it includes participant's right to fair treatment and right to privacy.

- **Right to Fair Treatment**

The investigator selected the study participants based on the inclusion and exclusion criteria and divided them into study and control group. Both the groups were given equal consideration with regard to the safety, privacy, aseptic technique throughout the study period.

- **Right to Privacy**

The investigator maintained the participant's privacy by performing Swedish massage in the treatment room only and through confidentiality pledge obtained through informed written consent from the caregivers and assent from children.

(D) CONFIDENTIALITY

The investigator maintained confidentiality of the data provided by the study participants and caretakers through individual coding for each participant.

3.1.3 RELIABILITY

The reliability of the tool was established by Inter-rater method for level of CINV, where 10 children were selected and divided into study and control group. The reliability score was **r = 0.9** which was assessed by using Karl Pearson's Correlation method. The 'r' value indicated that the tool shows highly positive correlation. Hence the tool was considered highly reliable for proceeding with the main study.

3.14 PILOT STUDY

Pilot study is a trial run for the main study. The refined tool was used for pilot study to test the feasibility and practicability.

Formal administrative approval was obtained from the ICCR and Principal, Omayal Achi College of Nursing. The investigator had got official administrative approval from Hospital administrators and the data collection procedure was done at Anand Hospital, Surat. A brief introduction about self and purpose of study was explained to caregivers and informed written consent was obtained. Confidentiality regarding the data was assured so as to get co operation throughout the procedure of data collection period.

Data collection was done for a one week and the investigator worked from morning 9 am to 6 pm for the completion of scheduled intervention. Based on the stratification of demographic data collected and inclusive and exclusive criteria, 10 samples were selected by using non probability purposive sampling technique, 5 samples in study group and 5 samples in control group were selected. The investigator performed Swedish massage along with Hospital routine for the study group and only Hospital routine for control group. The investigator assessed the level of CINV using Rhodes Index of Nausea and Vomiting for all the selected samples. The study group was given intervention of Swedish massage for 3 consecutive days by following strict aseptic techniques.

To begin with, the investigator performed the intervention 24 hours before chemotherapy, 30 minutes prior to chemotherapy and 24 hours after chemotherapy. The study group was given the intervention once a day along with the Hospital routine (standard antiemetic drugs) and the control group was allowed to follow Hospital routine (standard antiemetic drugs).The post test was conducted 24 hours after each day's intervention for 3 consecutive days by using modified Rhodes Index of Nausea and Vomiting and the results were interpreted.

3.15 PROCEDURE FOR DATA COLLECTION

Data collection procedure was done at Anand Hospital,Surat. Formal administrative approval was obtained from ICCR and Principal, Omayal Achi College of Nursing, the Administrators, Medical Director of Anand Hospital, Surat.

A brief introduction about self and purpose of the study was explained to caregivers and informed consent was obtained, thorough and clear explanation about the

intervention was given to the caregivers, confidentiality regarding the data was assured so as to get cooperation throughout the procedure of data collection

Data collection was done for a period of one month and the investigator worked from morning 9 am to 6 pm for completion of scheduled intervention. Based on the stratification of demographic data collected and inclusive and exclusive criteria, 60 samples were selected using Non probability purposive sampling technique, depending upon the number of case admissions on daily basis. The children were given the intervention in the treatment room after thoroughly following strict aseptic techniques.

The investigator prepared the room for the procedure by maintaining a warm room temperature and privacy. The investigator asked the children to undress till the chest level and lie down on the cot in prone position. After performing hand hygiene and adorning face mask the Swedish massage was given to the study group by applying mild pressure onto the child's skin as follows:

The investigator used her palm, stroked the child from the buttocks up to the shoulder and then moved downward to the buttocks with less pressure. Then the investigator used her thumb to oppose finger, knead and stroke the right half of the back with her right hand, knead and stroke the left half of the back with her left hand. Started from buttocks moved towards the child's shoulder and then again moved down the back. The investigator used fleshy sides (proximal) of her hands lightly striking the back from the buttocks upto the shoulder and repeated it. Next, the investigator used the thumb pads or fingertips and applied deep, circular movement near joints and other bony areas along the sides of the spine from the buttocks upto the spine of the child. Lastly, the investigator pressed the child on the back and upper limbs and ended by rapidly shaking using mild pressure same as shown in the table given on page number 33. During the intervention, thorough asepsis was maintained by regular hand washing before and after the intervention. The investigator performed the procedure 24 hours before chemotherapy, 30 minutes prior to chemotherapy and 24 hours after chemotherapy for 3 days. The study group (30 children with cancer) were given the intervention along with Hospital routine and control group (30 children with cancer) were allowed to follow only the Hospital routine (standard antiemetic drugs) .After the procedure the children were dressed and allowed to perform their routine activities.

Post test was conducted for both study and control group 30 minutes prior to chemotherapy and 24, 48 hours after chemotherapy by using Modified Rhodes Index of `Nausea and Vomiting for 3 days. Daily time schedule of the intervention was maintained for each sample in order to maintain continuity and to avoid confusion.

3.16 PLAN FOR DATA ANALYSIS

The data was analyzed using both descriptive and inferential statistics.

3.16.1 Descriptive Statistics

1. Frequency and percentage distribution was used to analyze the demographic data of children with cancer.
2. Mean and standard deviation was used to assess the post test level of CINV among children with cancer in study and control group.

3.16.2 Inferential Statistics

1. Paired ‘t’ test was used to compare the data within the study and control group.
2. Unpaired ‘t’ test was used to compare the data among children with cancer between study and control group.
3. Correlation Coefficient was used to find out the relationship of post test mean score of Chemotherapy Induced Nausea with Chemotherapy Induced Vomiting among children with cancer in study and control group.
4. One way Analysis of Variance (ANOVA) was used to associate the selected demographic variables with the post test mean score of CINV among children with cancer in study and control group.

CHAPTER – 4

DATA ANALYSIS AND INTERPRETATION

DATA ANALYSIS AND INTERPRETATION

This chapter deals with analysis and interpretation of the data to study the effectiveness of Swedish massage on level of CINV among children with cancer at selected Hospital, Surat. The data collected from 60 children with cancer was organized, tabulated and analyzed according to the objectives and plan for data analysis using descriptive and inferential statistics. The findings were presented under the following sections.

ORGANIZATION OF THE DATA

Section 4.1: Description of demographic variables among children with cancer in study and control group.

Section 4.2: Assessment and comparison of post test level of Chemotherapy Induced Nausea and Vomiting among children with cancer in study and control group.

Section 4.3: Correlation of the post test mean score of Chemotherapy Induced Nausea with Chemotherapy Induced Vomiting among children with cancer in study and control group.

Section 4.4: Association of selected demographic variables with the post test mean score of Chemotherapy Induced Nausea and Vomiting among children with cancer in study and control group.

SECTION 4.1: DESCRIPTION OF DEMOGRAPHIC VARIABLES AMONG CHILDREN WITH CANCER IN STUDY AND CONTROL GROUP.

Table 4.1.1: Frequency and percentage distribution of demographic variables among children with cancer in study and control group with respect to age in years, gender, religion and weight.

N=60

S.No.	Demographic variables	Study Group (n=30)		Control Group (n=30)	
		Swedish massage + Antiemetic drug		Antiemetic drugs	
		No.	%	No.	%
1.	**Age in years**				
	6	1	3.3	1	3.3
	7	5	16.7	5	16.7
	8	-	-	-	-
	9	2	6.7	2	6.7
	10	4	13.3	4	13.3
	11	**9**	**30.0**	**9**	**30.0**
	12	**9**	**30.0**	**9**	**30.0**
2.	**Gender**				
	Male	**18**	**60.0**	**20**	**66.7**
	Female	12	40.0	10	33.3
3.	**Religion**				
	Hindu	**16**	**53.3**	**18**	**60.0**
	Christian	11	36.7	10	33.3
	Muslim	2	6.7	1	3.3
	Others	1	3.3	1	3.3
4.	**Weight in kgs**				
	≤ 30	6	20.0	4	13.3
	31-40	-	-	2	6.7
	41-50	1	3.3	1	3.3
	51-60	5	16.7	2	6.7
	61-70	**9**	**30.0**	10	33.3
	≥71	**9**	**30.0**	**11**	**36.7**

The above table 4.1.1 shows that majority of the children with cancer were within the age group of 9 and 10 years being predominantly males and Hindus, who weighed ≥71 kgs in both the study and control group.

Table 4.1.2: Frequency and percentage distribution of demographic variables among children with cancer in study and control group with respect to height, type of cancer, total number of chemotherapy cycles prescribed, duration of present chemotherapy, n^{th} number of cycle . N=60

S.No.	Demographic variables	Study Group (n=30)		Control Group (n-=30)	
		Swedish massage +Antiemetic drugs		Antiemetic drugs	
		No.	%	No.	%
1.	**Height in cms**				
	126-135	1	3.3	3	10.0
	136-145	1	3.3	1	3.3
	146-155	5	16.7	2	6.7
	156-165	7	23.3	10	33.3
	166-175	**11**	**36.7**	**11**	**36.7**
	≥176	-	-	-	-
2.	**Type of cancer**				
	ALL	**26**	**86.6**	**21**	**70**
	AML	3	10	8	26.6
	Lymphoma	1	3.33	1	3.3
	Others	-	-	-	-
3.	**Total number of chemotherapy cycles prescribed**				
	1 cycle	-	-	-	-
	2 cycles	-	-	-	-
	3 cycles	-	-	-	-
	4 cycles	-	-	-	-
	4 cycles and above	**30**	**100.0**	**30**	**100.0**
4.	**Duration of present chemotherapy**				
	Below 1 week	**-**	**-**	**-**	**-**
	1-2 weeks	3	10.0	1	3.3
	2-3 weeks	**14**	**46.7**	**19**	**63.3**
	3-4 weeks	8	26.7	9	30.0
	4 weeks and above	5	16.7	1	3.3
5.	**n^{th} number of cycle**				
	1^{st} cycle	5	16.7	2	6.7
	2^{nd} cycle	8	26.7	6	20.0
	3^{rd} cycle	--	-	7	23.3
	4^{th} cycle and above	**17**	**56.7**	**15**	**50.0**

The above table 4.1.2 shows that most of the children with cancer were with a height between 166-175cm diagnosed with ALL having more than 4 cycles with around 2-3 weeks of duration who were in their 4^{th} cycle and above in both the study and control group**.**

Table 4.1.3: Frequency and percentage distribution of demographic variables among children with cancer in study and control group with respect to type of chemotherapeutic agent, antiemetic drugs, time and type of diet consumed prior to chemotherapy, previous history of cancer in the family, presence of caregiver during chemotherapy, home remedies. **N=60**

S.No.	Demographic Variables	Study Group (n=30)		Control Group (n-=30)	
		Swedish massage + Antiemetic drugs		Antiemetic drugs	
		No.	%	No.	%
1.	**Type of chemotherapeutic agent**				
	Highly emetogenic agents	5	16.7	3	10.0
	Moderately emetogenic agents	**21**	**70.0**	**25**	**83.3**
	Low emetogenic agents	4	13.3	2	6.7
	Minimally emetogenic agents	-	-	-	-
2.	**Antiemetic drugs**				
	5-HT_3 antagonist + dexamethasone +aprepitant	2	6.7	4	13.3
	5-HT_3 antagonist+dexamethasone	10	33.3	8	26.7
	5-HT_3 or dopamine antagonist	1	3.3	1	3.3
	Corticosteroid +Dexamethasone	**16**	**53.3**	**15**	**50.0**
	Others	1	3.3	2	6.7
3.	**Time of food consumption prior to chemotherapy**				
	Below 20 minutes	6	20.0	5	16.7
	20-40 minutes	**19**	**63.3**	**21**	**70.0**
	40-60 minutes	5	16.7	4	13.3
	Above 1 hour	-	-	-	-
4.	**Type of diet consumed by prior to chemotherapy**				
	Solid diet	**25**	**83.3**	**25**	**83.3**
	Liquid diet	5	16.7	5	16.7
	Bland diet	-	-	-	-
5.	**Previous history of cancer in the family**				
	Present	2	6.7	3	10.0
	Absent	**28**	**93.3**	**27**	**90.0**
6.	**Presence of caregiver during chemotherapy**				
	Present	**30**	**100**	**30**	**100.0**
	Absent	-	-		
7.	**Home remedies**				
	Follows home remedies	-	-	-	-
	Does not follow remedies	**30**	**100**	**30**	**100.0**

The above table 4.1.3 shows that majority of the children in both study and control group took moderately emetogenic drugs with Corticosteroid + Dexamethasone who consumed solid diet, 20-40 minutes prior to chemotherapy and predominantly did not have previous history of cancer in the family. All the caregivers were present during chemotherapy and none of them followed any home remedies.

SECTION 4.2: ASSESSMENT AND COMPARISON OF POST TEST LEVEL OF CINV AMONG CHILDREN WITH CANCER IN THE STUDY AND CONTROL GROUP.

n=30

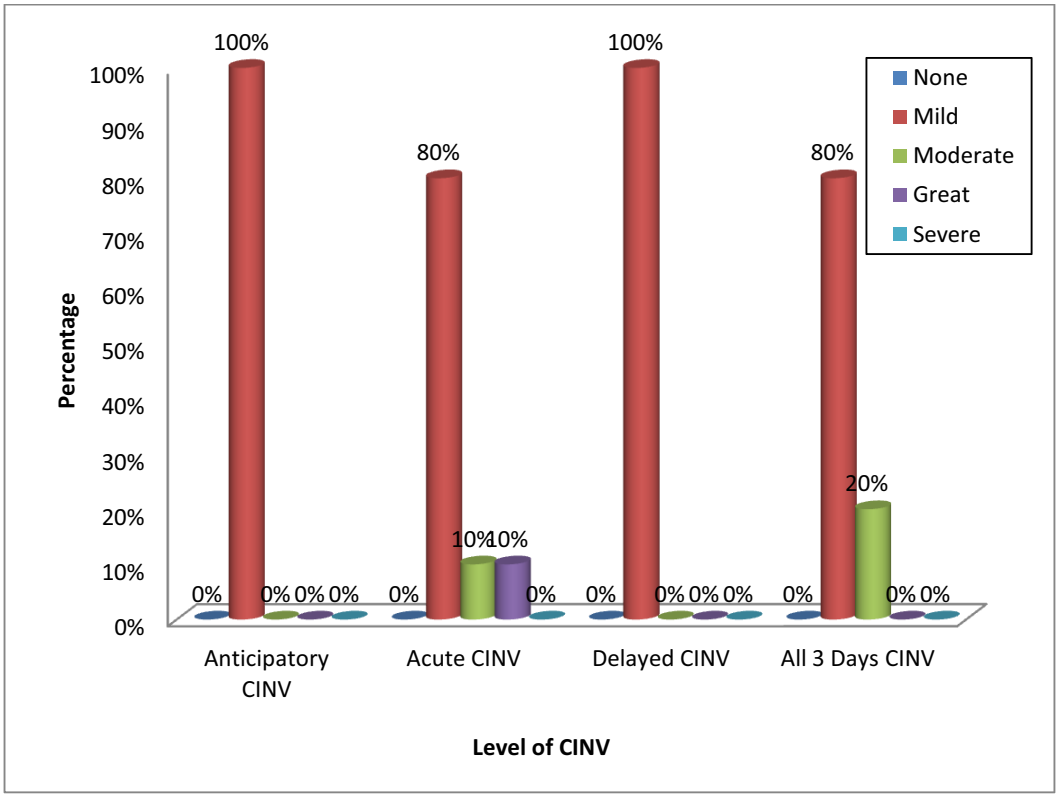

Fig.4.2.1: Percentage distribution of post test level of CINV among children with cancer in study group.

The above figure 4.2.1 shows that children with cancer who were given Swedish massage and standard antiemetic measures experienced mild level of anticipatory CINV, acute CINV and delayed CINV. While combining all the three days score most of the children with cancer experienced mild level of CINV and few experienced moderate level of CINV.

n=30

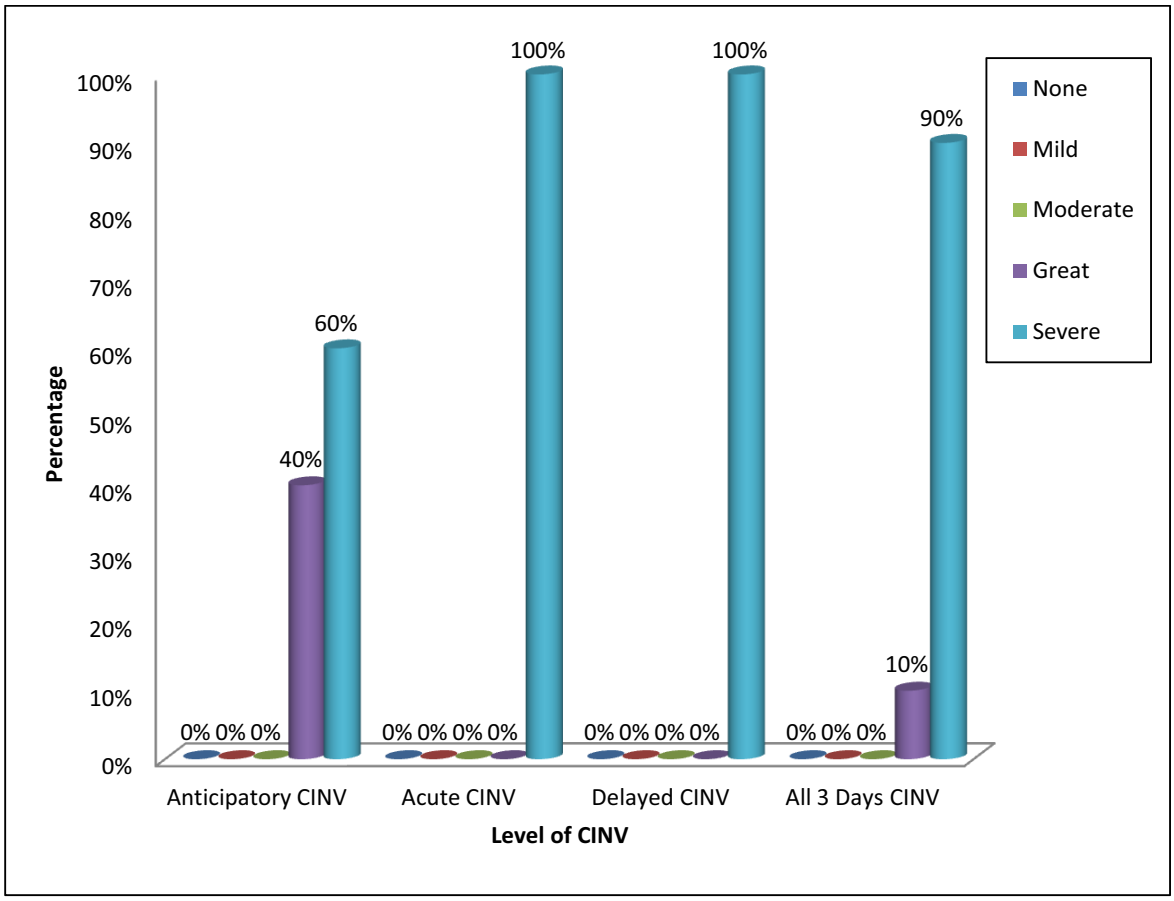

Fig.4.2.2: Percentage distribution of post test level of CINV among children with cancer in control group

The above figure 4.2.2 shows that majority of children who received only standard antiemetic drugs had experienced severe and great level of anticipatory CINV, acute CINV, delayed CINV While combining all the three days score most of the children had experienced severe level of CINV.

Table 4.2.3: Comparison of post test mean score of CINV among children with cancer between the study and control group. N=60

Variables	Study group- Swedish massage(n=30)		Control group – Antiemetic drugs(n=30)		Unpaired 't' test value
Anticipatory nausea	4.60	1.06	15.6	2.57	**-21.72**
Anticipatory vomiting	4.06	2.58	24.5	2.28	**-32.48**
Anticipatory CINV	8.70	2.90	40.4	4.03	**-34.95**
Acute nausea	4.03	2.28	16.3	1.66	**-45.39**
Acute vomiting	4.20	1.51	24.3	1.82	**-56.78**
Acute CINV	8.23	2.28	40.6	1.66	**-23.83**
Delayed nausea	3.80	1.34	17.8	1.76	**-46.44**
Delayed vomiting	4.66	1.42	26.7	1.61	**-56.11**
Delayed CINV	8.46	1.34	44.5	1.76	**-34.46**
All 3 day nausea	12.5	3.64	50	4.92	**-33.48**
All 3 day vomiting	12.9	3.98	75.2	4.35	**-57.82**
All 3 days CINV	25.4	5.29	125.2	7.98	**-57.03**

***High statistical Significance at $p<0.001$ level.

The above table 4.2.3 shows that the post test mean score of CINV and standard deviation in children with cancer who underwent Swedish massage was significantly less than the post test mean score of CINV among the children with cancer who underwent only Hospital routine (standard antiemetic drugs). The calculated unpaired 't' test values were found to be highly statistical significant at $p<0.001$ level which indicates that the children with cancer receiving chemotherapy were given Swedish massage in the study group had significant reduction in level of CIN, CIV and CINV during anticipatory, acute, delayed and all the 3 days episodes .

SECTION 4.3: CORRELATION OF THE POST TEST MEAN SCORE OF CIN WITH CIV AMONG CHILDREN WITH CANCER IN STUDY AND CONTROL GROUP.

Table 4.3.1: Correlation of post test mean score of CIN with CIV among children with cancer in the study group.

n=30

Variables	Anticipatory Vomiting		Acute Vomiting		Delayed Vomiting		All 3 days vomiting	
	'r'	p	'r'	p	'r'	p	'r'	P
Anticipatory Nausea	.060	.753	.221	.241	**.363***	**.049**	.253	.178
Acute Nausea	-.281	.133	.078	.683	**.524****	**.003**	.034	.857
Delayed Nausea	**-.629****	**.000**	-.013	.944	.287	.123	-.311	.095
All 3 days Nausea	**-.414***	**.023**	.105	.582	**.567****	**.001**	-.026	.892

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

p = Level of significance.

The above table 4.3.1 shows that delayed and all 3 days nausea were negatively correlated with anticipatory vomiting whereas anticipatory nausea, acute nausea and all 3 days nausea were positively correlated with delayed vomiting which was highly statistically significant at $p < 0.05$ and $p < 0.01$ level respectively in the study group.

Table 4.3.2: Correlation of post test mean score of CIN with CIV among children with cancer in the control group.

n=30

Variables	Anticipatory Vomiting		Acute Vomiting		Delayed Vomiting		All 3 days Vomiting	
	'r'	**p**	**'r'**	**p**	**'r'**	**p**	**'r'**	**P**
Anticipatory Nausea	.242	.198	.156	.409	.110	.562	.221	.240
Acute Nausea	**.422***	**.020**	.189	.318	**.366***	**.046**	**.456***	**.011**
Delayed Nausea	**.402***	**.027**	.192	.309	.246	.190	**.588****	**.001**
All 3 days Nausea	**.453***	**.012**	.268	.152	.242	.197	**.479****	**.007**

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

p = Level of significance.

The above table 4.3.2 shows that acute nausea, delayed nausea, all 3 days nausea were positively correlated with anticipatory vomiting and acute nausea was positively correlated with delayed vomiting . Acute nausea, delayed nausea, all 3 days nausea were also positively correlated with all 3 days nausea which was highly statistically significant at $p<0.05$ and $p<0.01$ level respectively in the control group.

SECTION 4.4: ASSOCIATION OF SELECTED DEMOGRAPHIC VARIABLES WITH THE POST TEST MEAN SCORE OF CINV AMONG CHILDREN WITH CANCER IN STUDY AND CONTROL GROUP.

Table 4.4.1: Association of post test mean score of CINV with selected demographic variables among children with cancer in study group (One way Anova).

n=30

SNo.	CINV Scores	Anticipatory CINV		Acute CINV		Delayed CINV		All 3 Days CINV	
	Demographic Variables	**F**	**Sig.**	**F**	**Sig.**	**F**	**Sig.**	**F**	**Sig.**
1.	Age in years	.862	.521	**3.60**	**.014***	**3.81**	**.011****	1.27	.306
2.	Gender	2.23	.146	2.25	.144	3.27	.081	.375	.545
3.	Religion	1.61	.210	.147	.931	.595	.624	.319	.811
4.	Weight in kgs	.577	.682	**4.55**	**.007****	**3.88**	**.014***	1.63	.196
5.	Height in cms	.442	.815	**3.23**	**.022***	**2.95**	**.033***	1.25	.317
6.	Type of cancer	.647	.532	**12.7**	**.000*****	**6.38**	**.005****	**11.3**	**.000*****
7.	Total number of chemotherapy cycles prescribed	-	-	-	-	-	-	-	-
8.	Duration of present chemotherapy	.012	.998	.523	.671	.397	.756	.409	.748
9.	n^{th} number of cycle	.019	.981	.052	.949	.267	.768	.154	.858
10.	Type of chemotherapeutic agent	1.640	.213	.328	.723	.511	.606	1.32	.283
11.	Antiemetic drugs	.521	.721	2.59	.061	2.55	.064	1.68	.186
12.	Time of food consumption prior to chemotherapy	.227	.799	.986	.386	1.95	.161	1.61	.218
13.	Type of diet consumed by the child prior to chemotherapy	1.21	.280	1.01	.322	.644	.429	2.23	.146
14.	Previous history of cancer in the family	.022	.883	.014	.907	.119	.732	.024	.879
15.	Presence of caregiver during chemotherapy	-	-	-	-	-	-	-	-
16.	Home remedies	-	-	-	-	-	-	-	-

***- High statistical Significance at p<0.001, **-High Statistical significance at p<0.01 level, *- Statistical Significance at p<0.05 level.

The findings in the above table 4.4.1 revealed that there was high statistical significant association of selected demographic variables with regard to age in years, religion, height in cms in acute, delayed and all 3 days CINV in the study group.

n=30

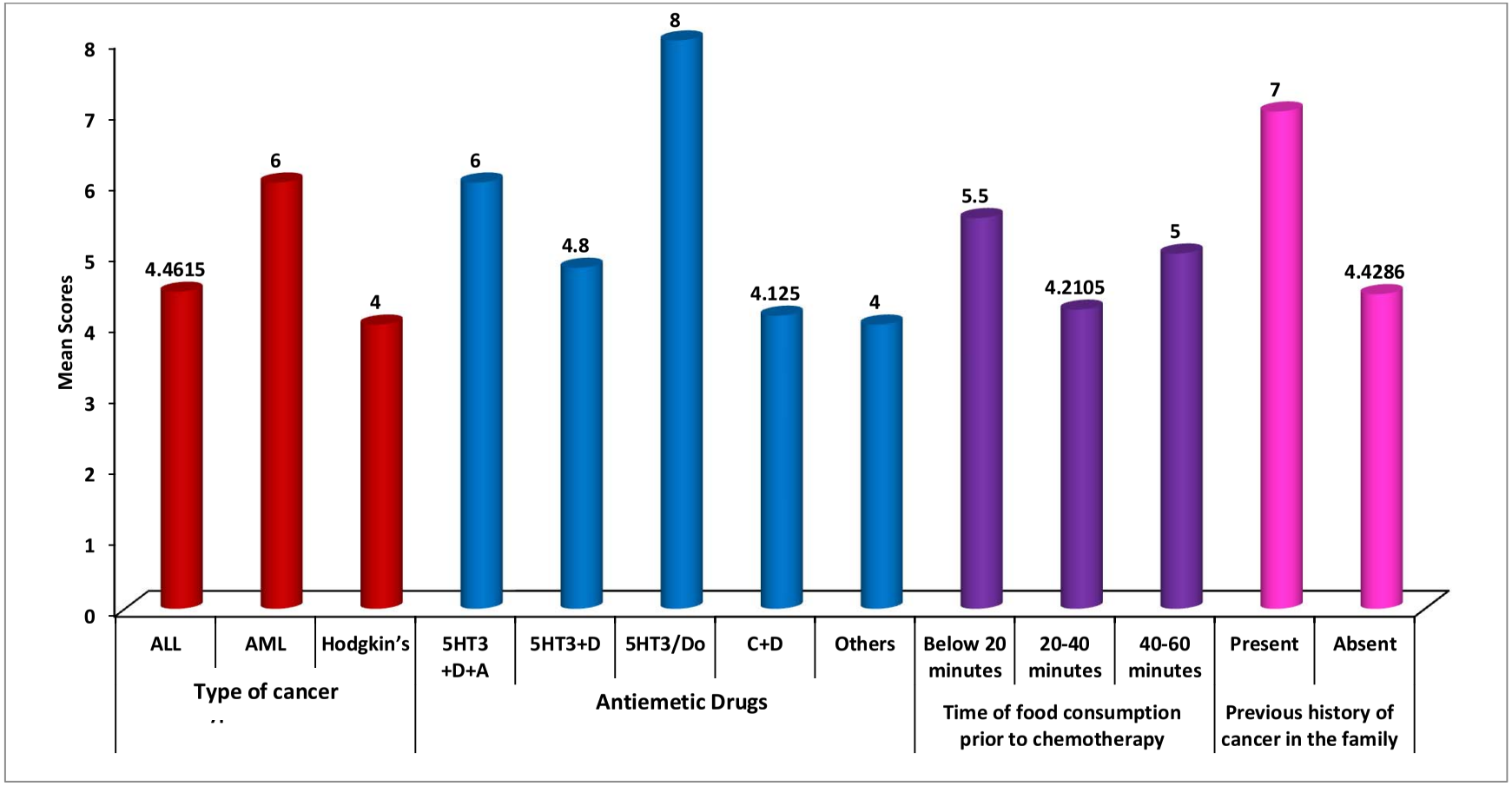

Fig.4.4.1.1: Association of post test mean score of Anticipatory Nausea with selected demographic variables among children with cancer in the study group (One way ANOVA).

n=30

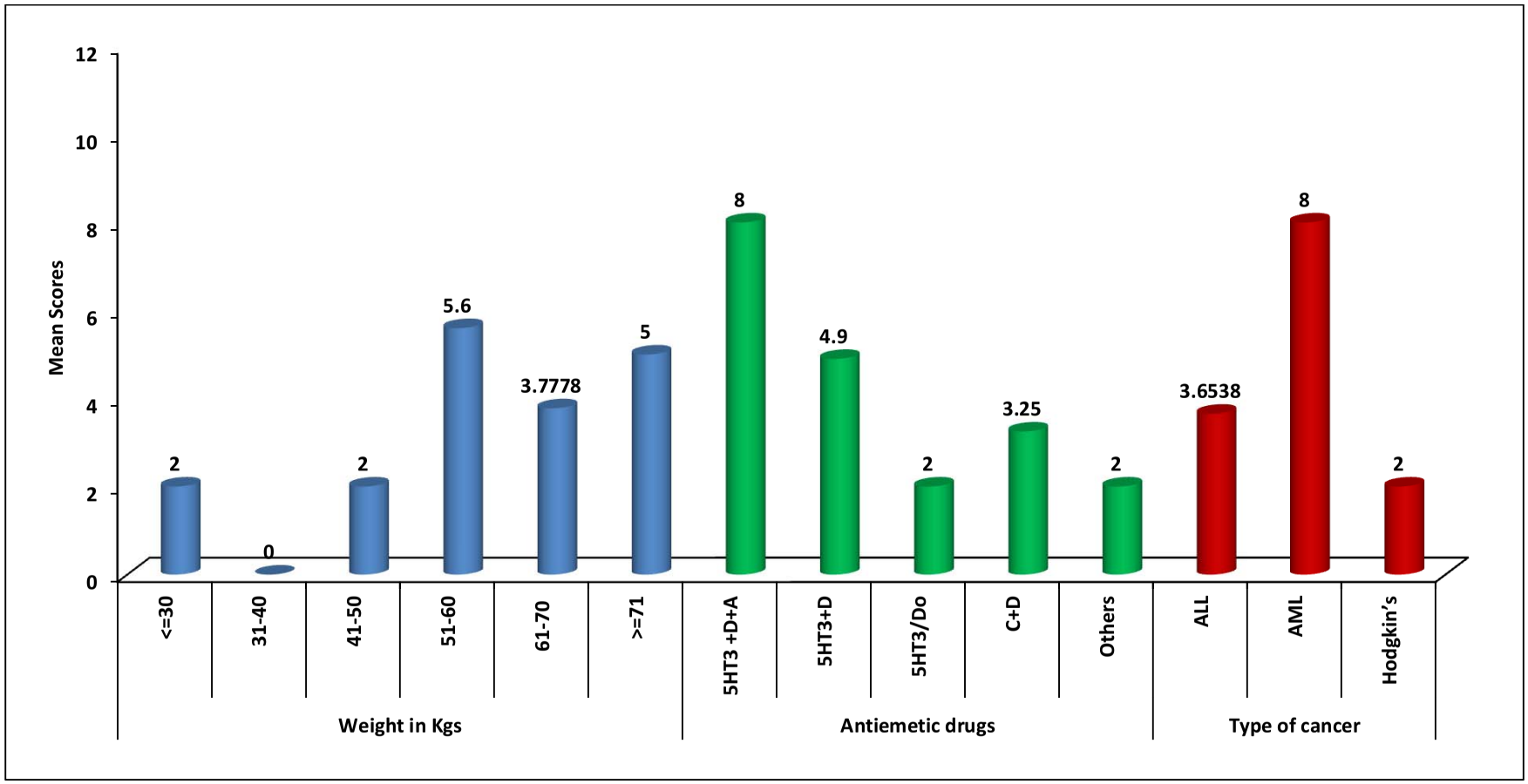

Fig.4.4.1.2: Association of post test mean score of Acute Nausea with selected demographic variables among children with cancer in the study group (One way ANOVA)

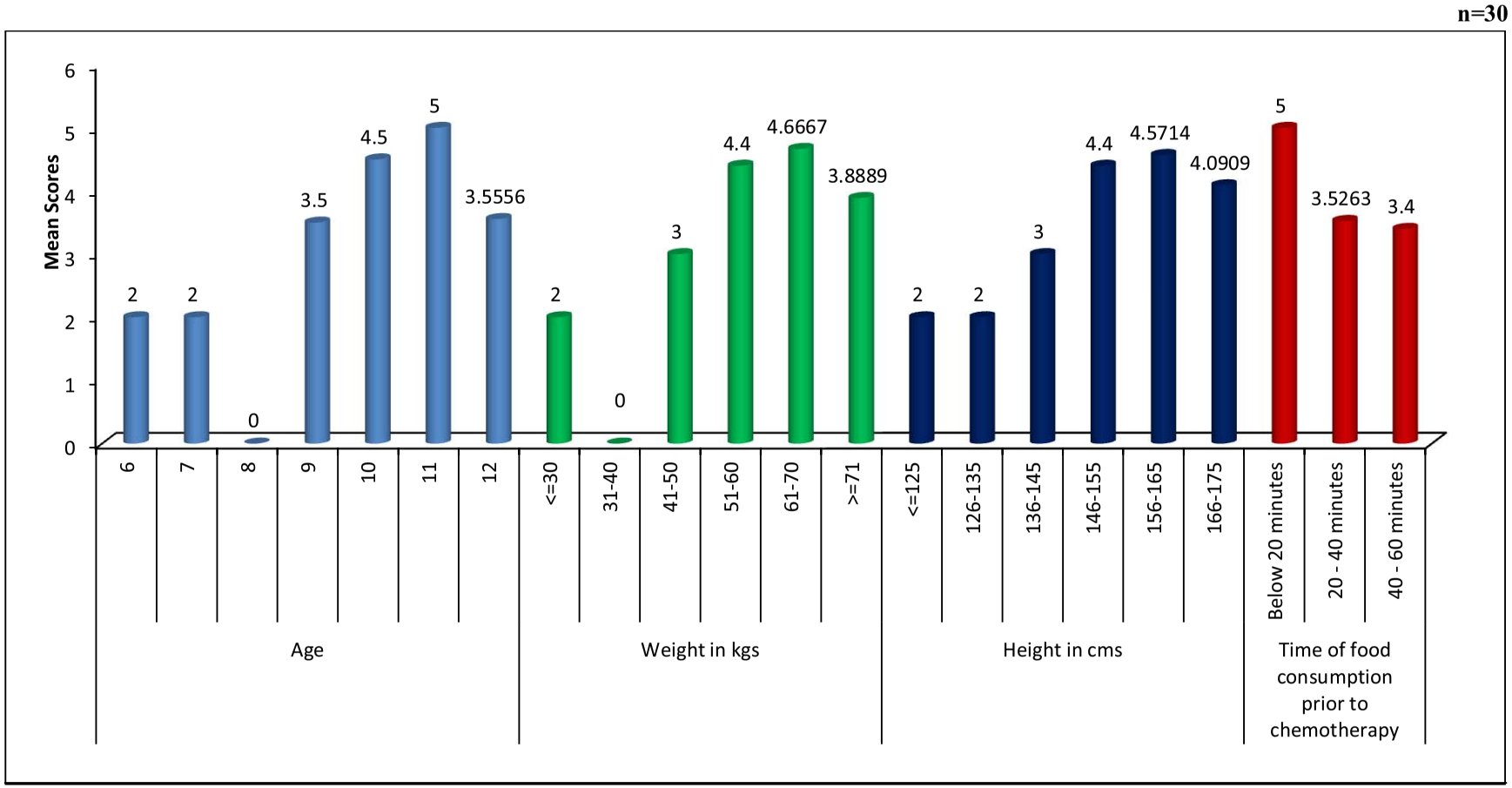

Fig.4.4.1.3: Association of post test mean score of delayed nausea with selected demographic variables among children with cancer in the study group.

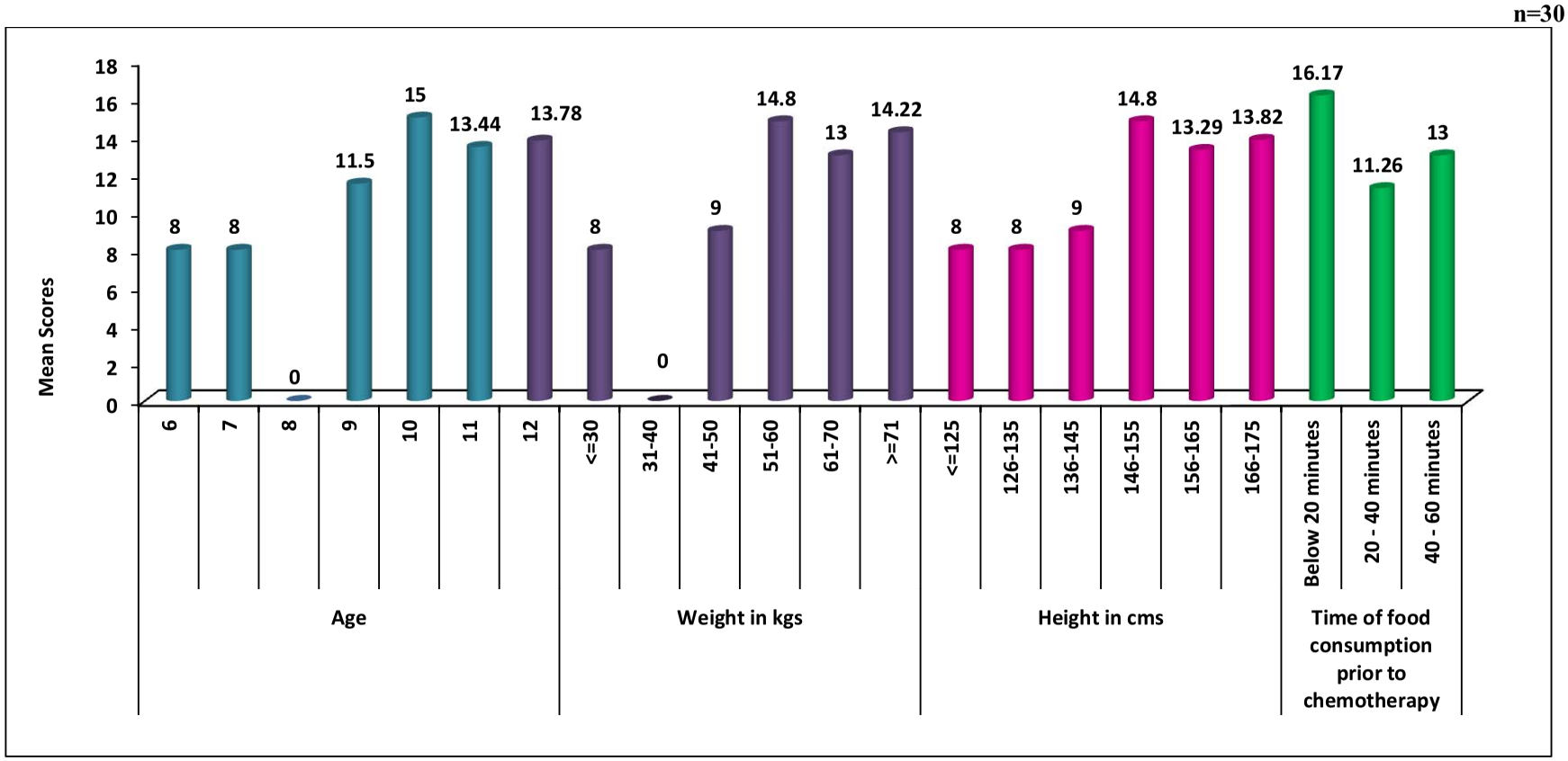

Fig.4.4.1.4: Association of post test mean score of all 3 days nausea with selected demographic variables among children with cancer in the study group

n=30

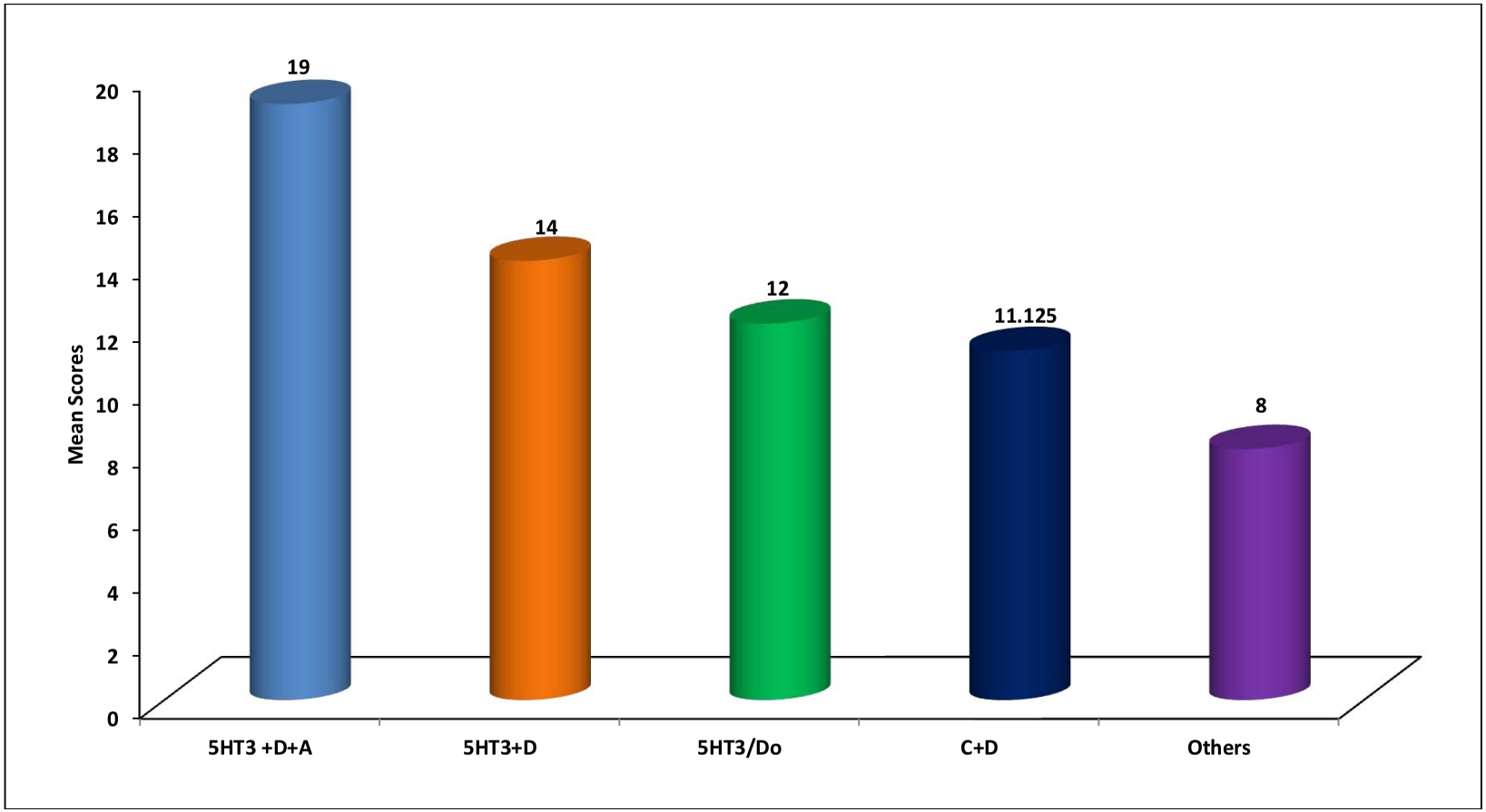

Fig.4.4.1.4.1: Association of post test mean score of all 3 days nausea with selected demographic variables among children with cancer in the study group.

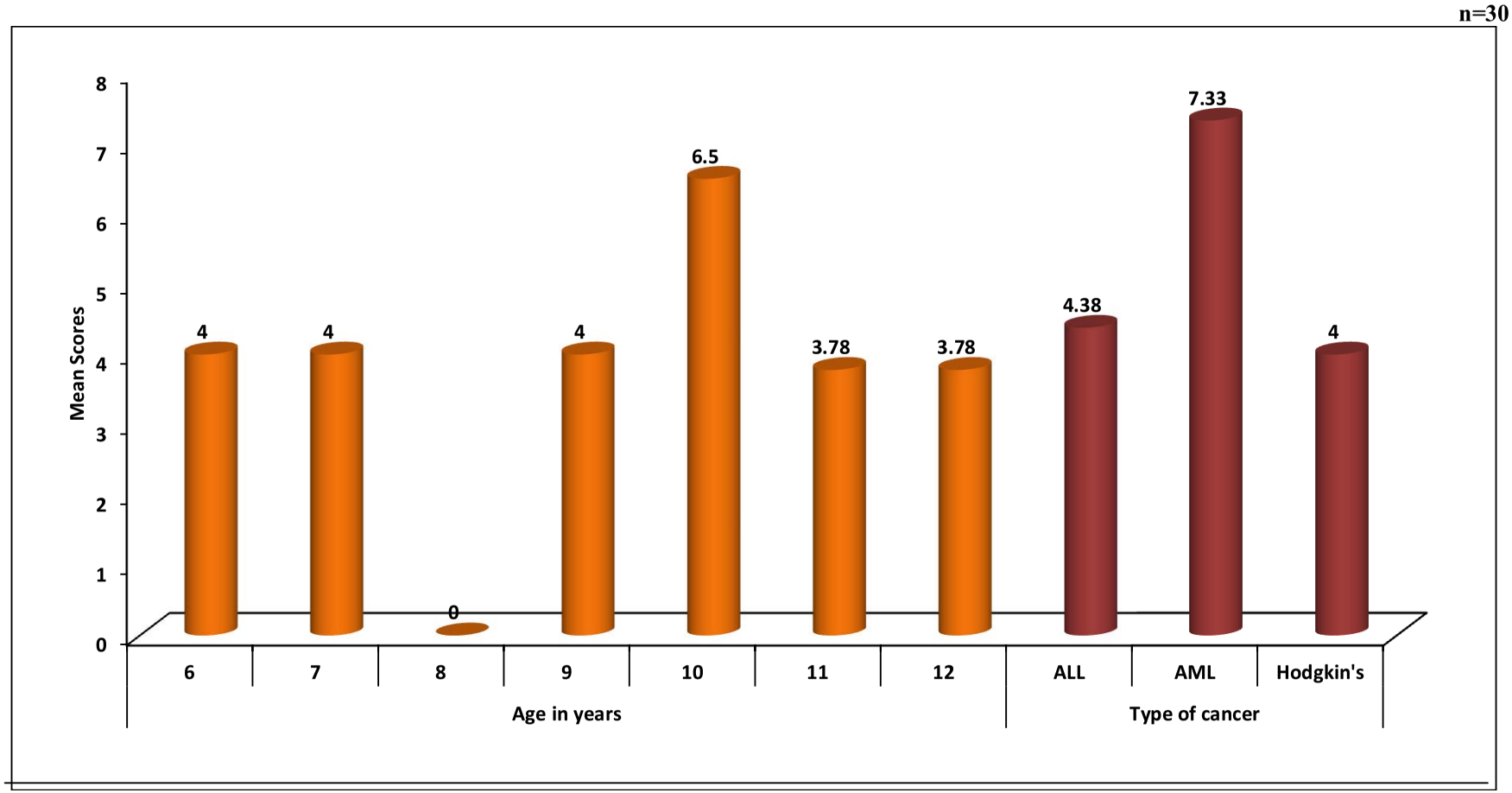

Fig.4.4.1.5: Association of post test mean score of acute vomiting and delayed vomiting with selected demographic variables among children with cancer in the study group.

n=30

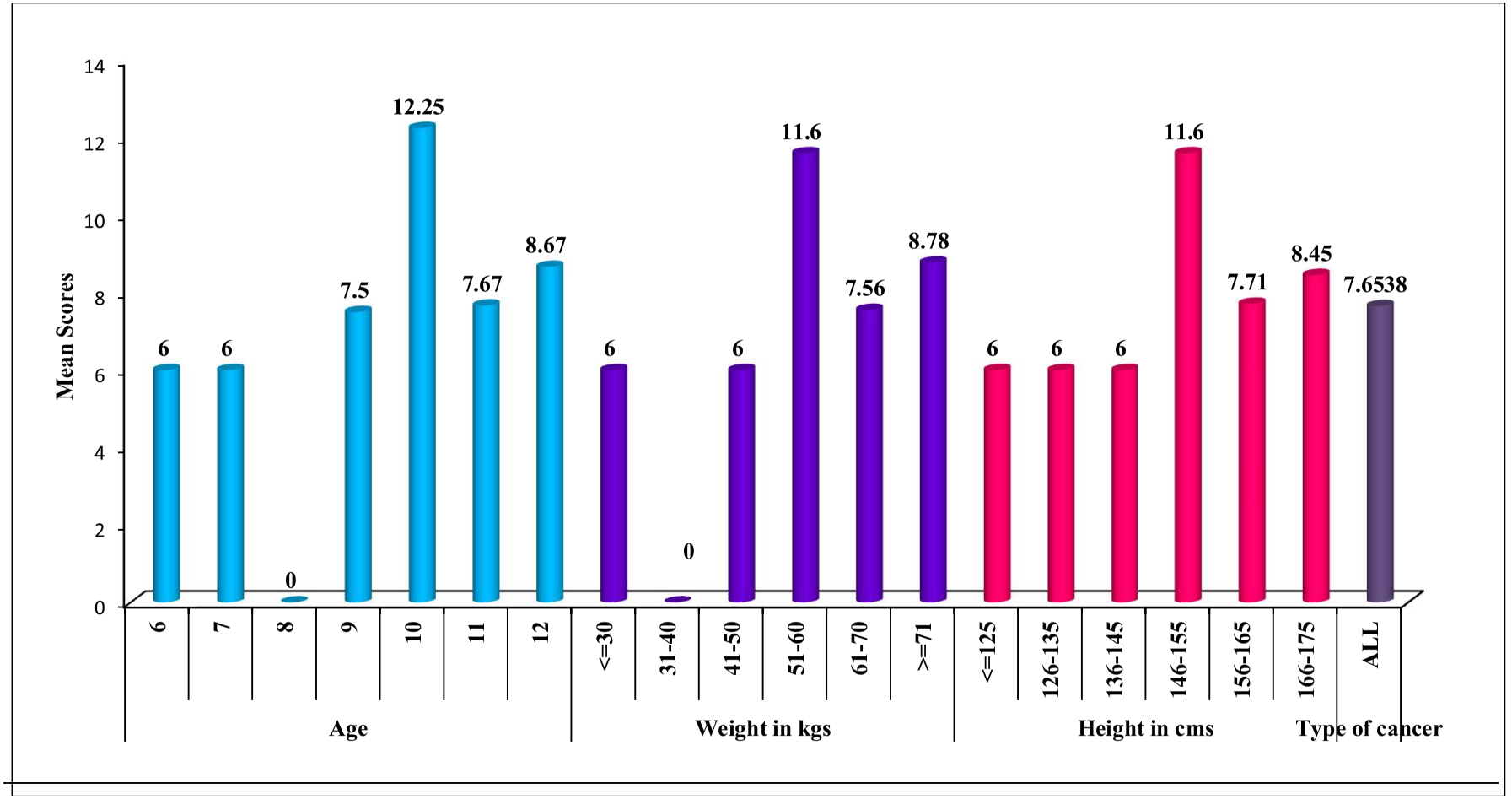

Fig.4.4.1.6: Association of post test mean score of acute CINV with selected demographic variables among children with cancer in the study group

n=30

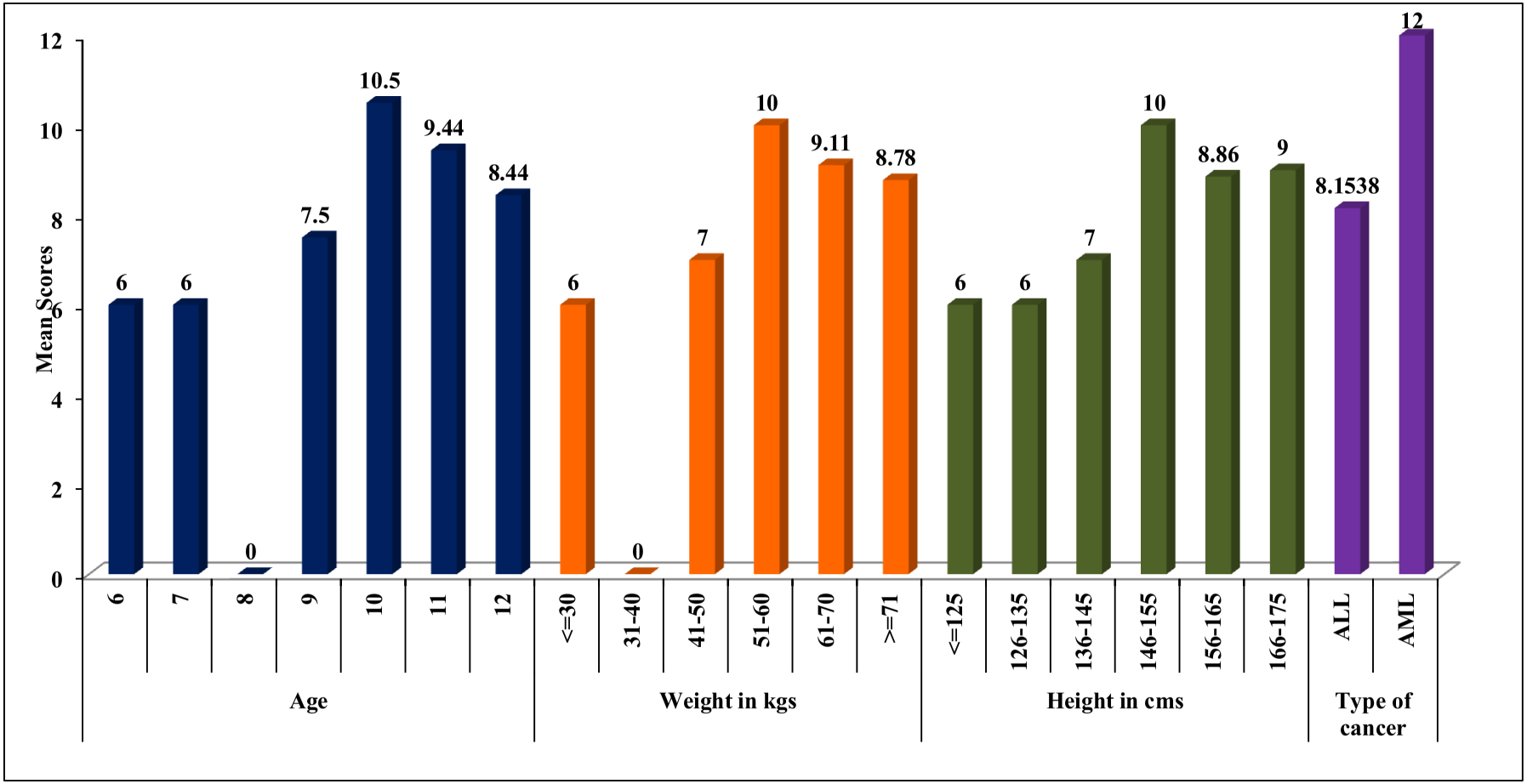

Fig.4.4.1.7: Association of post test mean score of delayed CINV with selected demographic variables among children with cancer in the study group

Description for the figures :

The figure 4.4.1.1 shows that the children with AML receive highly emetogenic drugs for which they were given either of the two drugs 5 HT_3serotonin receptor antagonist which works both centrally on the CTZ and peripherally on vagus by blocking it, or dopamine receptor antagonist which acts on dopamine receptors in the CTZ and on peripheral receptors to accelerate gastric emptying. The children who consumed food below 20 minutes would not have started their digestion process yet they receive stimuli from the CTZ and finally with regard to previous history of cancer, they are aware of the experiences regarding chemotherapy and it's after effects and caretakers might also take certain precautionary measures. Due to all these reasons anticipatory nausea is associated with these selected demographic variables in the study group who received Swedish massage 24 hours prior to chemotherapy.

The figure 4.4.1.2 shows that acute nausea had highly statistical significant association with children weighing 51- 60 kgs as they have an increase in muscle mass along with which Swedish massage also being given half an hour prior to chemotherapy. Pertaining to antiemetic drugs and type of cancer children with AML receive highly emetogenic drugs comparatively; for which combination of 3 drugs $5HT_3$+ Dexamethasone +Aprepitant are given.5 HT_3serotonin receptor antagonist which works both centrally on the CTZ and peripherally on vagus by blocking it and Aprepitant is a substance P antagonist which blocks the signals given off by NK1 receptors therefore decreasing the likelihood of vomiting in children clearly exhibiting the association with nausea episodes.

The figure 4.4.1.3 shows delayed nausea in the study group had high statistical significant association with age, height and weight because all these 3 non modifiable variables are interrelated, with an increase in age there is increase in height and weight contributing to increase in body surface area which indirectly increases the drug dosages and improves effectiveness of Swedish massage given 24 hours prior to chemotherapy. With regard to time of food consumption prior to chemotherapy, the children who consumed food below 20 minutes had experienced anticipatory nausea and are more likely to experience delayed nausea even after 48 hours after chemotherapy like a carryover effect as it is concerned mostly with ones feelings and experiences.

The figure 4.4.1.4 shows that all 3 days nausea among children with cancer in the study group had high statistical significant association with age, weight, height and time of food consumption prior to chemotherapy.

The figure 4.4.1.4 and 4.4.1.4.1 shows that all 3 days nausea among children with cancer in the study group had high statistical significant association with age, weight, height, antiemetic drugs. All these 3 non modifiable variables are interrelated, with an increase in age there is increase in height and weight contributing to increase in body surface area which indirectly increases the drug dosages and improves effectiveness of Swedish massage given 24 hours prior to chemotherapy. With regard to time of food consumption prior to chemotherapy, the children who consumed food below 20 minutes had experienced anticipatory nausea and delayed nausea contributing to this association in all 3 days nausea.

The figure 4.4.1.5 shows that acute vomiting among children with cancer in the study group had high statistical significant association with age in years as the dosage of antiemetic drugs increases with age and younger children do not know to control vomiting nor verbalize the urge to vomit to take immediate action. The figure also shows that acute vomiting among children with cancer in the study group had high statistical significant association with regard to type of cancer ,Acute Myeloid Leukemia and Acute Lymphocytic Leukemia receive highly emetogenic drugs wherein the children do not tend to tolerate and thereby experienced delayed vomiting adding to this children who experienced acute nausea would have progressed to delayed vomiting usually in the 4^{th} and 5^{th} day inspite of long acting antiemetic drugs and Swedish massage which might be due to the of nature of cancer.

The figure 4.4.1.6 shows acute CINV among children with cancer in the study group had high statistical significant association with age, weight, height and type of cancer because based on these non modifiable variables the chemotherapy drug and antiemetic drug dosages are decided along with which Swedish massage is given 30 minutes prior to chemotherapy in reducing the level of CINV, which may be experienced within 24 hours after chemotherapy.

The figure 4.4.1.7 shows that delayed CINV among children with cancer in the study group had high statistical significant association with age, weight, height and type of cancer because based on these non modifiable variables the chemotherapy drug and antiemetic drug dosages are decided along with which Swedish massage being given 24 hours after chemotherapy in reducing the level of CINV, which may be experienced 24 and 48 hours after chemotherapy.

Table 4.4.2: Association of post test mean score of CINV with selected demographic variables among children with cancer in control group (One way Anova).

n=30

S.No.	CINV Scores	Anticipatory CINV		Acute CINV		Delayed CINV		All 3 Days CINV	
	Demographic Variables	**F**	**Sig.**	**F**	**Sig.**	**F**	**Sig.**	**F**	**Sig.**
1.	Age in years	**2.68**	**.046***	**3.82**	**.011****	**4.16**	**.007****	**3.09**	**.027***
2.	Gender	.225	.639	**6.90**	**.014***	1.13	.296	1.49	.232
3.	Religion	.445	.723	.967	.423	1.69	.192	.721	.549
4.	Weight in kgs	.856	.525	1.07	.401	**2.61**	**.050***	1.18	.345
5.	Height in cms	.926	.481	1.27	.309	**2.54**	**.056***	1.31	.292
6.	Type of cancer	.349	.708	.129	.879	.085	.919	.429	.655
7.	Total number of chemotherapy cycles prescribed	-	-	-	-	-	-	-	-
8.	Duration of present chemotherapy	.404	.751	.127	.943	.191	.902	.444	.724
9.	n^{th} number of cycle	.569	.641	.295	.829	.548	.654	.233	.872
10.	Type of chemotherapeutic agent	.031	.969	.145	.866	1.05	.362	.548	.584
11.	Antiemetic drugs	.470	.758	.119	.975	1.05	.398	.510	.729
12.	Time of food consumption prior to chemotherapy	.783	.467	1.15	.331	1.06	.360	.046	.955
13.	Type of diet consumed by the child prior to chemotherapy	.717	.404	**4.17**	**.051***	.058	.812	.298	.590
14.	Previous history of cancer in the family	**4.13**	**.051***	.810	.376	.129	.723	1.59	.217
15.	Presence of caregiver during chemotherapy	-	-	-	-	-	-	-	-
16.	Home remedies	-	-	-	-	-	-	-	-

*** - High statistical Significance at p<0.001, ** -High Statistical significance at p<0.01 level, * - Statistical Significance at p<0.05 level.

The findings in the above table 4.4.2 revealed that there was high statistical significant association of selected demographic variables with regard to age in years with anticipatory, acute, delayed CINV and gender with acute CINV, weight in kgs and height in cms with delayed CINV and type of diet consumed prior to chemotherapy with acute CINV and previous history of cancer in family with anticipatory CINV.

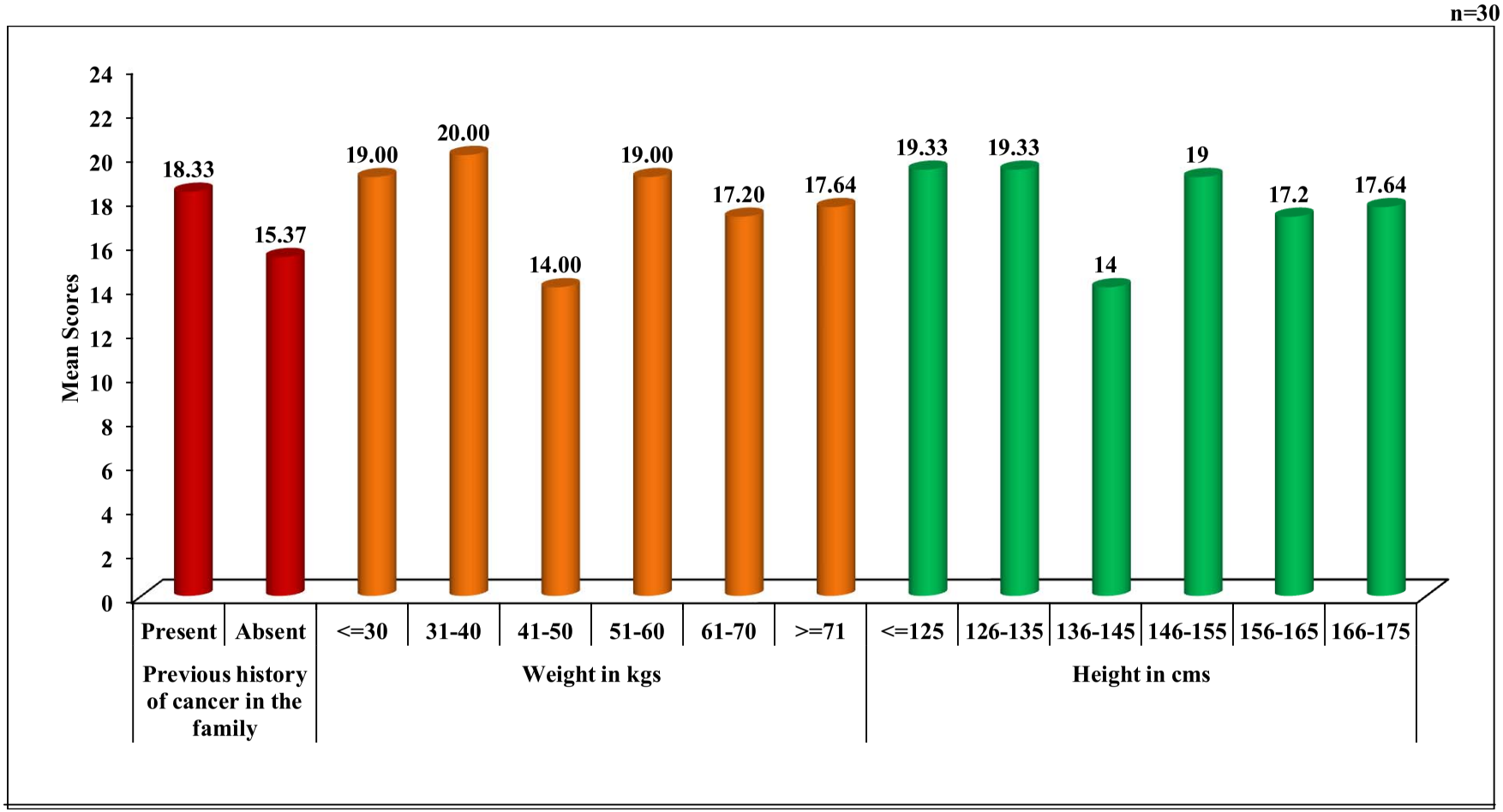

Fig.4.4.2.1: Association of post test mean score delayed nausea with selected demographic variables among children with cancer in the control group.

n= 30

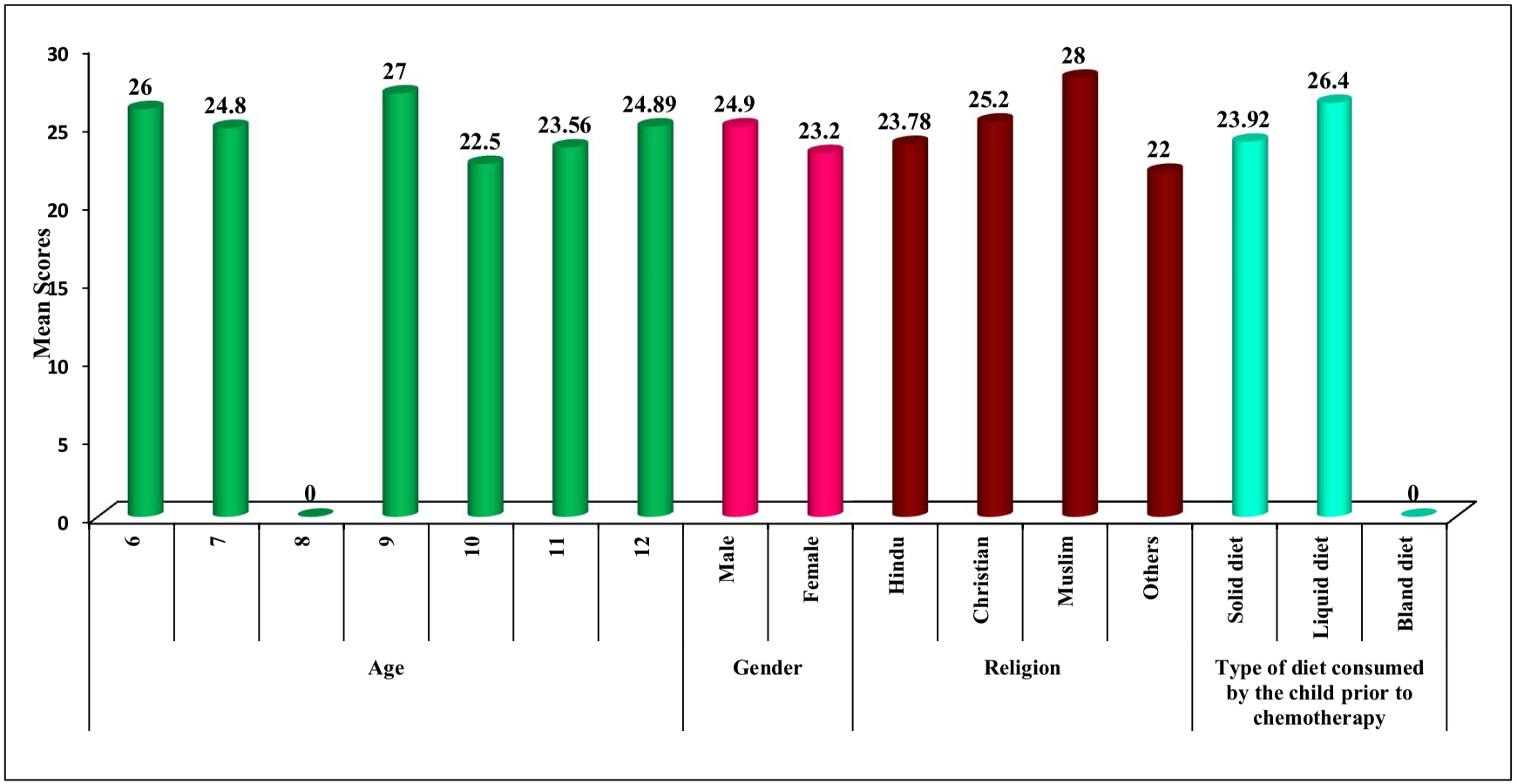

Fig.4.4.2.2: Association of post test mean score of acute vomiting with selected demographic variables among children with cancer in the control group.

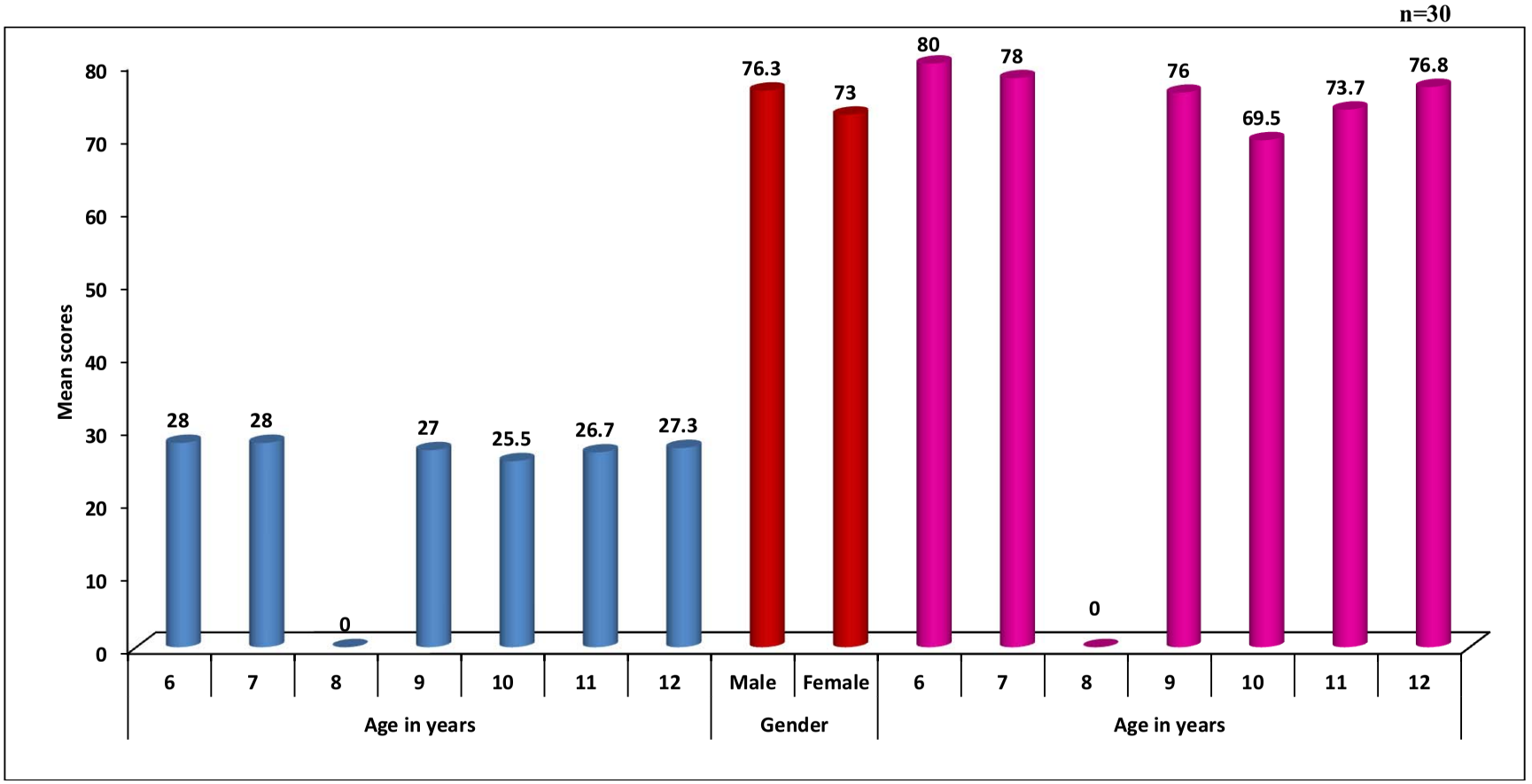

Fig.4.4.2.3: Association of post test mean score of delayed vomiting and all 3 days vomiting with selected demographic variables among children with cancer in the control group.

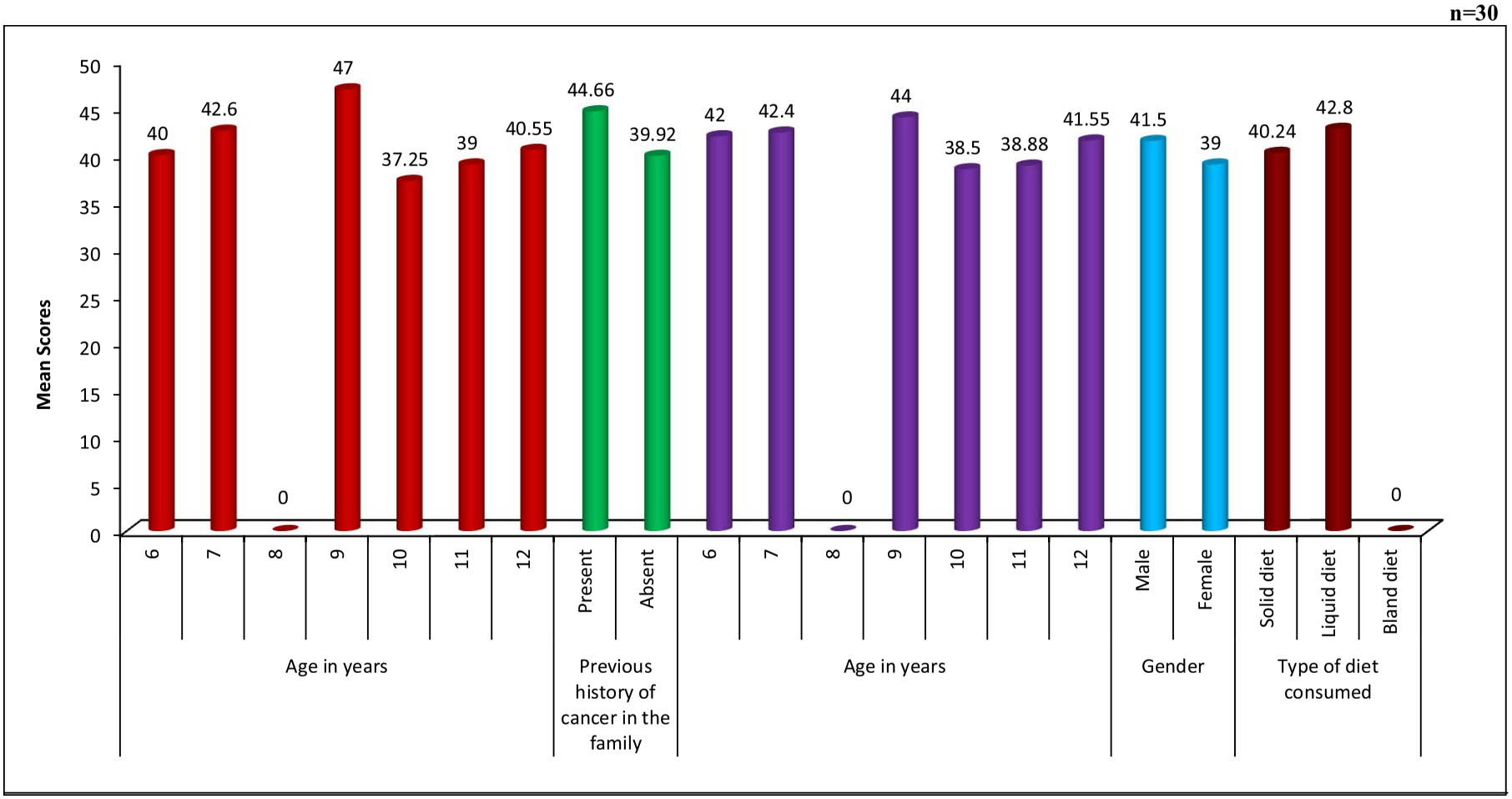

Fig.4.4.2.4: Association of post test mean score of anticipatory CINV and Acute CINV with selected demographic variables among children with cancer in the control group

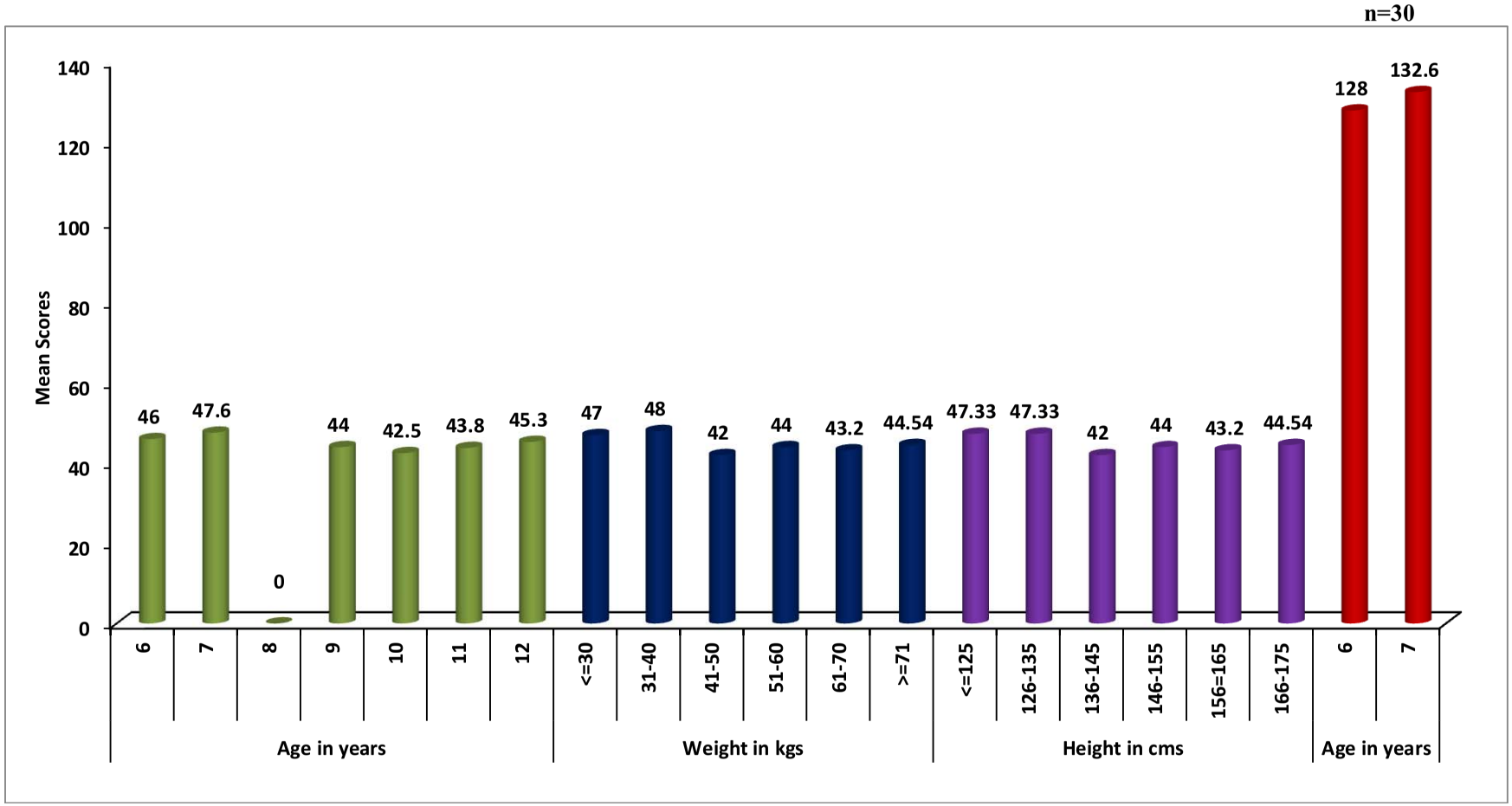

Fig.4.4.2.5: Association of post test mean score of delayed CINV and All 3 days CINV with selected demographic variables among children with cancer in the control group.

Description for the above figures:

The figure 4.4.2.1 shows that anticipatory nausea in the control group had high statistical significant association with previous history of cancer in family, since the child would have grown up seeing the family members experiencing CINV. The figure also shows that anticipatory vomiting had high statistical significant association with age in years because as the age increases children tend to be more matured and are aware of the happenings surrounding him experiencing vomiting.

The figure 4.4.2.2 shows that delayed nausea among children with cancer in the control group had high statistical significant association with height and weight of the children as the dose of chemotherapeutic drug increases and since they have already anticipated nausea. Now after the introduction of drug into the body they exhibit delayed nausea adding onto this they are even get triggered by stimuli from CTZ and are deprived of Swedish massage ultimately experiencing delayed nausea.

The figure 4.4.2.3 shows that children with delayed vomiting in the control group had high statistical significant association with respect to age and gender the reason being increase in body surface area with age and males have already experienced acute vomiting are more prone to delayed vomiting too. The figure also shows that all 3 days vomiting had high statistical significant association with age as younger children experienced higher level of CIV as they do not tend to manage multiple changes in their body comparatively thereby highly triggering the CTZ.

The figure 4.4.2.4 shows that anticipatory CINV in the control group had high statistical significant association with age in years and previous history of cancer because their anticipation increases with their past experiences and being aware of the consequences of chemotherapy. The figure also shows acute CINV in the control group had high statistical significant association with age, gender, type of food consumed prior to chemotherapy because male children and those who consumed liquid diet predominantly experienced acute CINV because with introduction of drug into the body triggering the higher cortical centers for nausea and vomiting center for vomiting along with regurgitation of food contents.

The figure 4.4.2.5 shows that delayed CINV among children with cancer in the control group had high statistical significant association with age, weight and height. The

figure also shows that all 3 days CINV in the control group had high statistical significant association with age in years. These non modifiable factors play a crucial role calculating the drug dosages thereby triggering nausea and vomiting.

CHAPTER – 5

DISCUSSION

DISCUSSION

This chapter discusses in detail the findings of the study as interpreted from the statistical analysis, in accordance with the objectives of the study and further discussion will illustrate the fulfillment of the objectives by the study findings. The purpose of the study was to assess the effectiveness of Swedish massage on level of CINV among children with cancer.

As per the stated objectives the findings of the study were discussed.

5.1 Description of the demographic variables among children with cancer in study and control group.

The demographic variables of both the study and control group shown in the table 4.1.1 to 4.1.3 depicts that majority of the children were within the age groups of 9 and 10 years predominantly being males and Hindus weighing ≥ 71 kgs with a height between 166-175 cms. Most of the children had Acute Lymphocytic Leukemia(ALL) who were prescribed above 4 cycles of chemotherapy with a duration of 2-3 weeks .They were in their 4^{th} cycle and above taking moderately emetogenic drugs and corticosteroid + dexamethasone as antiemetic agent. They consumed solid diet, 20-40 minutes prior to chemotherapy and none of them had followed any home remedies.

5.2 The first objective of the study was to assess and compare the post test mean score of CINV among children with cancer in study and control group.

The figure 4.2.1and 4.2.2 shows that majority of children with cancer in the study group had experienced mild level of anticipatory, acute, delayed and all 3 days CINV whereas in the control group majority of them had experienced severe level of anticipatory, acute, delayed and all 3 days CINV.The investigator identified that in the study group children were retained in the mild level of CINV (Children who were in the range of 1-36 score in the Modified Rhodes Index of Nausea and Vomiting) due to the effect of Swedish massage and antiemetic drugs. In control group the children experienced severe level of CINV (children who were in the range of 109 -144 score in the Modified Rhodes Index of Nausea and Vomiting) in all the 3 days in spite of administration of antiemetic drugs. This infers that the schedule maintained for giving the Swedish massage does have a drastic effect on reducing CIN, CIV and all 3 days CINV. The massage given on the first day (24 hours prior to chemotherapy) has an impact in reducing the anticipatory component of CIN and CIV which being a response to conditioned stimuli such as the smells, sights, and sounds of hospital. The massage given on second day (30 minutes prior to chemotherapy) also shows to have an impact for the next 24 hours by maintaining in the mild level of CINV and finally on the third day (24 hours after chemotherapy). Swedish massage had aided the child to maintain in

mild level of CINV which has contributed to remarkable changes in the children cancer treatment and health status of children.

The table 4.2.1 showed the comparison of post test mean score of CINV between study and control group among children with cancer. Those who underwent Swedish massage had significantly less post test mean score of CINV than the children with cancer who underwent only hospital routine because the manipulation of muscles induces local biochemical changes which influence neural activity at the spinal cord segmental level and modulate activities of sub cortical nuclei that influence the vomiting center and higher cortical center in the brain that evokes a relaxation response thereby decreasing the stimuli from chemoreceptor trigger zone ultimately mitigating the adverse effect of chemotherapy- CINV. Prolonged duration and routine administration of Swedish massage might possibly induce more permanent neuro physiologic adaptations because of neural plasticity.

The calculated unpaired 't' test values were all found to be highly statistically significant at $p<0.001$ level. These values indicate that there was reduction in the post test level of CINV among children with cancer who received the intervention (Swedish massage) than the post test level of CINV among children with cancer who were allowed to follow hospital routine on ethical basis.

Thus the null hypothesis NH_1 stated earlier that "**There is no significant difference between the post test level of CINV among children with cancer in study and control group at $p < 0.05$ level." was rejected.**

Seyedreza Mazlum, Narges Toghian Chaharsoughi, Abdolah Banihashem and Hamidreza Behnam Vashani (2013) conducted a randomized control trial among 70 children within the age group of (4-18 years) they randomly selected 35 in study and control group respectively. Swedish massage was given 24 hours and 30 minutes prior to chemotherapy and 24 hours after chemotherapy for 20 minutes. To explore the effect of Swedish massage post test was done 24 hours after each day's intervention by using visual analogue scale and BARF scale along with questionnaire. The findings revealed that incidence of CINV were significantly reduced than that of the control group at $p>0.05$ level, hence Swedish massage is a simple non- pharmacological nursing measure that reduces nausea and vomiting which nurses can effectively practice in the clinical settings.

The conceptual framework adopted for this study was Kolcoba's theory of comfort, which supported the study and was helpful for the investigator to accomplish the study in an integrated approach. At the beginning, the investigator identified CINV during chemotherapy as the health care need of the children with cancer based on the

identified need the investigator planned Swedish massage as the comforting measure which led to the attainment of enhanced comfort through relief (Level of CINV), ease (Swedish massage), transcendence (Reduction in the level of CINV) which was assessed by post test level of CINV. Institutional integrity was formulated for best practices and best policies.

5.3 The second objective was to correlate the post test mean score of Chemotherapy Induced Nausea with Chemotherapy Induced Vomiting among children with cancer in study and control group.

The findings of the study were analyzed by using Karl Pearsons 'r' to calculate the correlation between CIN with CIV. The table 4.3.1 shows that delayed and all 3 days nausea were negatively correlated with anticipatory vomiting this depicts that when CIN increases, the level of CIV decreases in the study group which explains that although the children in study group had increased mean score of CIN but due to the effect of Swedish massage CIV had been reduced. Whereas anticipatory nausea, acute nausea and all 3 days nausea were positively correlated with delayed vomiting which clearly explains that with an increase in anticipatory nausea, acute nausea and all 3 days nausea there is an increase in delayed vomiting too. All the correlations were highly statistically significant at $p < 0.05$ and $p< 0.01$ level respectively in the study group.

Swedish massage induces relaxation response via parasympathetic nervous system involving the digestive system, the stimulated nerve endings innervate the autonomic nervous system which in turn innervates GI tract releasing endorphins, neurotransmitters and hormones evoking a decreased stimuli from CTZ and connecting the massage signals separately to limbic system, vomiting centers and higher cortical centers which brought about the individual differences in the CIN and CIV episodes and changes in the correlations between them.

The tables 4.3.2 shows that acute nausea, delayed nausea, all 3 days nausea were positively correlated with anticipatory vomiting and acute nausea was positively correlated with delayed vomiting due to the impact of confounding variables. Acute nausea, delayed nausea, all 3 days nausea were also positively correlated with all 3 days nausea this depicts that when CIN increases, the level of CIV also increases although they were given antiemetic drugs as a hospital routine. All the correlations were highly statistically significant at 0.05 and 0.01 level respectively in the control group.

Jolie.N.Haun and John Graham Pole (2010) conducted a randomized non blinded prospective study on Children with Cancer and Blood Diseases Experience Positive Physical and Psychological Effects from Massage Therapy. The participants were within the age group of 6- 17 years; the study group received Swedish massage for 20 minutes

once daily for a period of 4 days for inpatients, or once a week for 4 weeks for outpatients. The control group did not receive any intervention. The results indicated that there was reduction in the nausea scores but vomiting incidence in both the groups showed no statistical significant difference (p= 0.192).

Hence the NH_2 stated earlier **"There is no significant correlation of post test mean score of Chemotherapy Induced Nausea with Chemotherapy Induced Vomiting among children with cancer in study and control group at p < 0.05 level." was rejected.**

5.4 The third objective was to associate the selected demographic variables with the post test mean score of CINV among children with cancer in study and control group.

The findings of the study were analyzed using one way Analysis of Variance for the association of demographic variables with the post test mean scores of CIN, CIV and all 3 days CINV. A total of 11 demographic variables were associated out of which 10 were non modifiable confounding variables. These non modifiable variables were interrelatedly woven together influencing the treatment regimen and level of CINV. Interestingly, most number of associations in the study and control group was with the age, weight and height comprehending them would add onto chemotherapeutic drugs and antiemetics.

The figure 4.4.1.1 to 4.4.1.4 shows the association of post test mean score of CIN in the study group, where anticipatory nausea was associated with type of cancer , antiemetic drugs, time of food consumption prior to chemotherapy, previous history of cancer; acute nausea was associated with weight , antiemetic drugs , type of cancer; delayed nausea was associated with age, height , time of food consumption prior to chemotherapy; finally all 3 days nausea was associated with age , weight , height , time of food consumption prior to chemotherapy. This revealed that in Acute Myeloid Leukemia, $5HT_3$ serotonin receptor antagonist and dopamine receptor antagonist accelerate gastric emptying and previous experiences in the family have greatly influenced anticipatory nausea. As the age increases the child's height, weight also increases contributing to increased body surface area having an impact on Swedish massage, important point to be noted here is that depending on the type of cancer chemotherapeutic drugs are calculated relying on the body mass index based on which the antiemetic drugs are prescribed. This clearly explains the reason behind most of the variables influencing the acute, delayed episodes of nausea.

The figure 4.4.1.5 shows that acute and delayed vomiting in the study group was associated with age and type of cancer respectively. Though antiemetic drugs and Swedish massage being given the nature of the disease is very much influencing even in

the delayed phases of CIV. The figure 4.4.1.6 to 4.4.1.7 shows that acute and delayed CINV in the study group were associated with age, weight, height and type of cancer because based on these non modifiable variables the chemotherapy drug and antiemetic drug dosages are decided along with which Swedish massage is given 30 minutes prior to chemotherapy to manage acute CINV and 24 hours after chemotherapy to manage delayed CINV, which may be experienced within 24 hours after chemotherapy.

The figure 4.4.2.1 to 4.4.2.2 shows that in the control group anticipatory nausea is associated with previous history of cancer as it being a learned response, anticipatory nausea has a strong psychological component and does not respond well to antiemetic prophylaxis or treatment. Delayed nausea being associated with age and height. The figure 4.4.2.3 to 4.4.2.4 shows that anticipatory vomiting was associated with age in years; acute vomiting was associated with age, gender, religion and children who consumed liquid diet; delayed vomiting was associated with age in years and gender; all 3 days vomiting with age in years.

The figure 4.4.2.5 to 4.4.2.6 shows that children in the control group have influential factors for anticipatory, acute, delayed and all 3 days CINV reveals non modifiable factors play a crucial role calculating the drug dosages thereby triggering nausea and vomiting adding to which introduction of drug into the body triggering the higher cortical centers for nausea and vomiting center for vomiting.

Basch et al (2014) conducted a study to update the ASCO guidelines(American Society of Clinical Oncology), a systematic review of the medical literature was done from MEDLINE and COCHRANE library, and Multinational Association for Supportive Cancer Care were all searched in which he clearly stated that highly emetogenic drugs used for AML were cytarabine and anthracycline drugs example –daunorubicin. Therefore there is a need in alterations in providing the dosage of antiemetic a well to handle nausea and vomiting.

Hence the NH_3 stated earlier **“There is no significant association of the selected demographic variables with the post test mean score of CINV among children with cancer in study and control group at $p<0.05$ level.” was rejected.**

In a study by Brandt et al (2011) it was reported that moderately massaging children back led to relaxation, emotional health, appetite improvement, and nausea and vomiting reduction in children with cancer receiving chemotherapy. It was shown in a study that Swedish massage in cancer children under chemotherapy decreases nausea and vomiting to 45% as compared to control group

Based on these results, the investigator recommends that nurses can effectively administer Swedish massage to alleviate CINV among children with cancer. Accordingly, children and their families will be trained in this regard. It is noteworthy that one of the main objectives of nursing care is to provide children with relaxation and peace.

CHAPTER – 6

SUMMARY, CONCLUSION, IMPLICATIONS, RECOMMENDATIONS AND LIMITATIONS

SUMMARY, CONCLUSION, IMPLICATIONS, RECOMMENDATIONS AND LIMITATIONS

This chapter puts forward the summary, conclusion, implications, and limitations of the study based on objectives selected.

6.1 SUMMARY

Children with cancer predominantly receive chemotherapy as it is the cornerstone of cancer therapy. Chemotherapy Induced Nausea and Vomiting is one of the adverse effects of chemotherapy which adversely affects the quality of life of a child. Swedish massage being proved to be easy and effective method, the researcher decided to adopt this intervention for this study. In order to reduce the incidence of complications due to chemotherapy and promote early and speedy recovery from CINV, the researcher conducted this study to assess the effectiveness of Swedish massage on the level of CINV among children with cancer at selected hospital, Surat. The findings of this study proved to be effective in reducing the level of CINV among children with cancer.

The objectives of the study were

1. To assess and compare the post test level of Chemotherapy Induced Nausea and Vomiting among children with cancer in study and control group.
2. To correlate the post test mean score of Chemotherapy Induced Nausea with Chemotherapy Induced Vomiting among children with cancer in study and control group.
3. To associate the selected demographic variables with the post test mean score of Chemotherapy Induced Nausea and Vomiting among children with cancer in study and control group.

The null hypotheses formulated were

NH_1- There is no significant difference between the post test level of Chemotherapy Induced Nausea and Vomiting among children with cancer in study and control group at $p < 0.05$ level.

NH_2- There is no significant correlation of post test mean score of Chemotherapy Induced Nausea with Chemotherapy Induced Vomiting among children with cancer in study and control group at $p < 0.05$ level.

NH_3- There is no significant association of the selected demographic variables with the post test mean score of Chemotherapy Induced Nausea and Vomiting among children with cancer in study and control group at $p<0.05$ level.

The review of literature was collected from varied primary and secondary sources, along with personal and professional experience and expert's opinion from the field of child health nursing provided a comprehensive framework for the selection of problem and for accomplishing the objectives of the study. It also contributed the ideas for framing the conceptual framework, methodology and for the development of the tool for data collection.

The conceptual framework employed for the study was derived from Kolcoba's theory of Comfort.

Quantitative research approach and quasi experimental research design was adopted by the nurse investigator to assess the effectiveness of Swedish massage on level of CINV among children with cancer. The research study was conducted among the children with cancer and whoever fulfilled the inclusion criteria at Anand hospital, Surat during the period of data collection. The sample size was 60 who were categorized using non probability purposive sampling technique and the samples were assigned into study and control group.

The data collection tool had 2 parts (data collection tool and intervention tool). Data collection tool had 2 sections

Section A: Demographic data

This includes age, weight in kgs, height in cms, gender, religion, type of cancer, duration of chemotherapy, total number of cycles prescribed, n^{th} number of cycle, type of the chemotherapeutic agent, antiemetic drugs, type of food consumed prior to chemotherapy, time of food consumption prior to chemotherapy, previous history of cancer in the family, presence of caregiver during chemotherapy, home remedies.

Section B: Modified Rhodes Index of Nausea and Vomiting.

The tool Modified Rhodes Index of Nausea and Vomiting is a patient or caregiver self-reported instrument to assess the objective and subjective factors of nausea and vomiting. The investigator explained the tool to the caregivers and obtained the subjective data from them, then the investigator coded objectively. The tool has got 8 questions related CIN and CIV and has been categorized as anticipatory, acute and delayed CINV. Thus this scale has been a great asset to the investigator to assess the CINV among children with cancer

The tool was validated by Medical and Nursing experts. Pilot study was conducted at Anand hospital, Surat and the results proved to be practicable and feasible to proceed with the main study. Inter-rater method was employed to establish the reliability of the tool for assessing the level of CINV by using Karl Pearson's coefficient correlation method by which the **r = 0.9** was obtained and thus the tool was found to be highly reliable for proceeding with the main study.

Throughout the research study the ethical aspect was maintained by obtaining the ethical clearance certificate from the International Centre for Collaborative Research (ICCR).Formal administrative approval was obtained from the hospital administrators and written informed consent from parents and assent from children was obtained. Privacy and confidentiality was pledged and was maintained throughout the full course of data collection period and the data collected were used only for the research purpose.

The main study data collection was conducted for a period of 4 weeks. The data collected during the main study was analyzed using SPSS version 13.

Main findings of the study revealed that

- Descriptive and inferential statistics were used to analyze the collected data. Interpretation and discussion were based on the objectives, null hypotheses, and conceptual framework and from various literature reviews.
- The post test level of CINV in the study group had exhibited values that most of the children were having mild(93.33%) to moderate(6.66%) level of CINV and in

the post test level of CINV in the control group exhibited that most of the children were having great(3.33%) and severe (96.66%)level of CINV.

- The comparison revealed that the mean score of post test level of CINV in study group was 25.433 with standard deviation of 5.29, whereas the mean score of post test level of CINV in control group was 125.20 with 7.98 as standard deviation in the control group. The calculated unpaired 't' test value t=-57.03 was found to be highly statistically significant at $p<0.001$ level. Hence Swedish massage was more effective in reducing CINV among children with cancer.
- The correlation revealed in the study group that, the post test mean score of Chemotherapy Induced Nausea was 12.533 with a standard deviation of 3.645 and the post test mean score of Chemotherapy Induced Vomiting was 12.933 with a standard deviation of 3.982.the calculated 'r' value of r = -.026 shows a negative correlation which was found to be statistically significant at $p < 0.05$ level. This clearly indicates that when the Chemotherapy Induced Nausea increases in the post test level of Chemotherapy Induced Vomiting does not necessarily increase.
- The association revealed that the post test mean score of level of all 3 days CINV was significantly associated with type of cancer in the study group and age in years was significantly associated in the control group.

6.2 CONCLUSION

The present study was aimed to assess the effectiveness of Swedish massage on level of CINV among children with cancer .The findings revealed that the post test mean score of the study group was 25.43 with standard deviation of 5.29 and mean score of control group was 125.20 with standard deviation of 7.98 .The calculated 't' value was -57.03, which indicated, that there was a high statistical significant difference in the post test level of CINV among children with cancer between study and control group at $P<0.001$ level. The results of the study revealed that Swedish massage was effective in reducing the level of CINV among children with cancer in the study group compared to the control group. The study findings also concluded that CIN and CIV have also significantly reduced thus the intervention tool can be utilized by the health care professionals in their clinical practice while caring for the children and the caretakers

must also be taught to practice as a routine at the chemotherapy wards in the cancer institute's.

6.3 IMPLICATIONS

The investigator has put forward the following implications from the study which is of crucial for nursing practice, nursing education, nursing administration and nursing research.

6.3.1 Nursing Practice

1. The pediatric nurses can adopt Swedish massage as an easy, efficient and safe method employed in care of children with cancer at their clinical area of practice.
2. The child health nursing practitioners can utilize this protocol for practicing Swedish massage in their daily routine.
3. The pediatric nurse should disseminate the information about Swedish massage to the caregivers of all children admitted in the health care settings.

6.3.2 Nursing Education

1. This research has been successfully implemented in Anand Hospital, Surat.
2. The child health nurse administrator along with the administrative bodies and other health agencies can devise a program to focus on the measures to control CINV.
3. The nurse administrator within the institution should motivate and train staff to carry out routine assessment of CINV using Modified Rhodes Index for Nausea and Vomiting and present an updated incidence of CINV and its impact.
4. The nurse administrator should investigate organizing Continuing Nursing Education, conferences and workshop on various trends of Swedish massage on reducing the level of CINV and other potential benefits.
5. The nurse administrator can allot separate budget for in service education to disseminate the research findings to all nurses at various affiliated institutions.
6. The nurse administrator can plan incentives or sponsorship for nurses undergoing training on Swedish massage.

6.3.3 Nursing Administration

1. This research has been successfully implemented in Anand Hospital, Surat.
2. The community health nurse administrator along with the administration bodies and other health care agencies can devise a program to focus on the measures to reduce the level of CINV.
3. The nurse administrator within the institution should motivate and train the staff to carry out routine assessment of level of CINV among children with cancer using Modified Rhodes Index of Nausea and Vomiting.
4. The nurse administrator should enforce in organizing Continuing Nursing Education, conferences and workshop on Swedish massage in reducing the level of CINV among children with cancer and other potential benefits.
5. The nurse administrator can allot separate budget for in service education to disseminate the research findings to all nurses at various affiliated institution.

6.3.4 Nursing Research

1. The findings of the study can be disseminated to the nurses working in various cancer institutions and student nurses through various media.
2. The generalization of the study results can be made further replication of the study in various settings and larger population.
3. More research can be done on the reduction in level of anxiety and other psychological aspects and other alternative methods of reducing level of CINV.

6.4 RESEARCH DISSEMINATION

1. Research findings of the main study were presented in the 4th International conference held at Omayal Achi College of Nursing, (2016).
2. Research results will be published in Online Journal of ICCR, www.iccrjnr.com.
3. Research findings will be put up in newspaper articles.

So, that nurses who read them can take initiative steps to implement such interventions in their hospital set up.

6.5 UTILIZATION OF RESEARCH FINDINGS

1. The research was successfully implemented in Anand Hospital, Surat.
2. A protocol on Swedish massage will be framed and utilized in various affiliated institutions and pamphlets will be issued to the mothers and the caregivers at the time of discharge as reinforcement.
3. Swedish massage will be implemented in the routine nursing care at various cancer hospitals and other affiliated cancer institutions.

6.6 RECOMMENDATIONS

The researcher presents strong recommendation to the nurses, social workers to involve actively in teaching Swedish massage on level of CINV among children with cancer which helps to prevent various other complications. The study recommends the following for the future research.

1. The researcher will recommend for implementing the Swedish massage in clinical area by the students of Omayal Achi College of nursing and its affiliated hospitals.
2. The researcher will recommend that the parents or the caregivers to be trained for the use of Swedish massage as part of routine care at clinical settings.
3. The study can be replicated with large samples in the same setting for reinforcement.
4. A comparative study can be conducted to compare the effectiveness of Swedish massage and other complimentary alternative measures.
5. A study can be conducted to assess the effectiveness of Swedish massage on the level of anxiety and other psychological parameters of children receiving chemotherapy.

6.7 LIMITATIONS

1. The investigator found difficulty in getting setting permission.
2. The investigator had difficulty in getting related Indian literatures.

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APPENDICES

APPENDIX – C

LETTER SEEKING EXPERT'S OPINION FOR CONTENT VALIDITY

From

Ms.Sowmiya.Rajendran
M.Sc (N) I year,
Omayal Achi College of Nursing,
45, Ambattur Road,
Puzhal, Chennai-66.

To

Respected Madam ,

Subject : Requisition for expert opinion regarding content validity

I am Ms.Sowmiya.Rajendran doing my M.Sc Nursing (2014-2016 Batch) specializing in Child Health Nursing at Omayal Achi College of Nursing under the guideship of Dr.S.Kanchana, Research Director, ICCR and speciality guide Mrs.Ruthrani Princely.J Head of the Department Child Health Nursing. As a part of my research project to be submitted to the Tamil Nadu Dr. M.G.R. Medical University February 2016 session and in partial fulfillment of the University requirement for the award of M.Sc Nursing degree, I am conducting **"A quasi experimental study to assess the effectiveness of Swedish massage on level of Chemotherapy Induced Nausea and Vomiting (CINV) among children with cancer at selected Hospital, Surat"** .I have enclosed my data collection and intervention tool for your expert guidance and validation.

Kindly do the needful.

Thanking you,

Yours faithfully,

Ms. Sowmiya.Rajendran.

Enclosures:

1. Research proposal
2. Data collection tool
3. Intervention tool
4. Content validity form
5. Certificate for content validity

LIST OF EXPERTS FOR CONTENT VALIDITY

MEDICAL EXPERTS:

1. **Dr. CHETAN. B .SHAH**
   M.D., D.C.H.,
   Senior Pediatrician,
   Anand Hospital, Timaliyawad,
   Athugar Street, Nanpura,
   Surat-395001, Gujarat.

2. **Dr.NIRAV. M.BUCH**
   Consultant Oncologist,
   Anand Hospital, Timaliyawad,
   Athugar Street, Nanpura,
   Surat-395001, Gujarat.

CHILD HEALTH NURSING EXPERTS:

1. **Dr.A.Judie, M.Sc.,(N),Ph.D.,**
   Dean, SRM College of Nursing,
   SRM University, SRM Nagar,
   Kattankulathur- 603 203

2. **Mrs.Nesa Sathya Satchi , M.Sc (N)**
   H.O.D, Child Health Nursing,
   Apollo College of Nursing,
   Ayanambakkam,
   Chennai-600095

APPENDIX – D

NO HARM CERTIFICATE FOR INTERVENTION

Name of the investigator : Ms. Sowmiya.Rajendran

Name of the intervention : Swedish massage

Purposes of Swedish massage :

→ To relieve from chemotherapy induced pain, anxiety, nausea, vomiting, retching, depression, fatigue and eating disorders.

→ To increase circulation, elimination of metabolic wastes, improve lymphatic drainage and immunity.

→ To support relaxation of body and mind and improve sleep.

→ To deliver more oxygenation to tissues which reduces muscle fatigue, soreness and stiffness.

→ To stimulate slower breathing and break up mucus and respiratory discharge in the lungs.

→ To promote better digestion, to relieve colic, gas and constipation.

Indications for Swedish massage :

→ Children undergoing chemotherapy.

→ Children experiencing Chemotherapy Induced Nausea, Chemotherapy Induced Vomiting, Chemotherapy Induced Retching and CINV.

→ Children undergoing chemotherapy experiencing severe pain, fatigue and anxiety, depression, eating disorders, stress.

Contraindications for Swedish massage :

→ Children diagnosed with psychosomatic disorders, skin infections, gastrointestinal and nervous system cancer, wilm's tumor and any other mass or surgery in the abdominal area.

→ Children having sore and injury in the massage area, metastasis.

→ Children under radiation therapy, Loss of consciousness.

Time : 20 minutes

Method : One to One method

Venue : Treatment room

Procedure:

Phase	Steps
Preliminary preparation	→ Place the child prone position with their upper garment removed upto the waist. → Perform hand hygiene and dry using sterile towel or tissue paper. → Wear personal protective equipment such as face mask and cap. → Warm hands by rubbing palm against palm.
Procedure	→ Apply mild pressure from the buttocks up to the shoulder and then move downward to the buttocks using 5 main strokes as follows : ➢ Effleurage - Long gliding strokes from the base of the spine to the shoulder. ➢ Petrissage- Gently lift the muscles away from bone, then roll and squeeze them again with gentle pressure from the base of the spine to the shoulder. ➢ Tapotment - Use the hands alternately to strike or tap the muscles from the base of the spine to the shoulder. ➢ Friction- Apply deep, circular transverse movements using thumb pads or fingertips near joints and other bony areas (the sides of the spine) from the base of the spine to the shoulder. ➢ Vibration- Press hands on the back from the base of the spine to the shoulder, and end by rapidly shaking for a few seconds.
Post procedure (After care)	→ Dress the child and allow to perform daily activities. → Wash your hands. → Document the procedure.

When to stop:

→ If the child refuses to continue Swedish massage, feels uncomfortable and alterations in vital signs are evident then, immediately the nurse or caregiver must stop the procedure.

Children with cancer in the study group will be given a safe, secure and comfortable Swedish massage. It is a very easy and cost effective nursing intervention in adjunction with the Hospital routine (Standard antiemetic measures). Swedish massage is given to reduce the level of CINV .The above mentioned intervention is a daily nursing procedures for those who receive chemotherapy and will not harm the children with cancer.

Signature with date:

Seal:

APPENDIX – G

INFORMED CONSENT REQUISITION FORM

From

Ms. Sowmiya.Rajendran

M.Sc Nursing (2014-2015)

Omayal Achi College of Nursing

Puzhal , Chennai - 6000066

To

The Mother / Caregiver of _____

ID.No._____

Chemotherapy Ward

Anand Hospital,

Surat.

Good Morning,

I Ms.Sowmiya. Rajendran, M.Sc Nursing (2014-2016 Batch) student from Omayal Achi College of Nursing, Chennai, conducting a quasi experimental study to assess the effectiveness of Swedish massage on level of Chemotherapy Induced Nausea and Vomiting among children with cancer at selected Hospital, Surat, as a partial fulfilment of the requirement for the degree of M.Sc. Nursing under The Tamil Nadu Dr. M.G.R. Medical University.

I assure you that information provided by you will be kept confidential. So, I request you to kindly cooperate with me and participate in this study by giving your frank and honest responses to the questions being asked.

Thank you.

Signature of the investigator

Sowmiya. Rajendran

PARENT INFORMED WRITTEN CONSENT FORM

I father or mother of _____ aged _____ understand that my child (younger than 18 years of age) being asked to participate in a research study conducted by Ms. Sowmiya.Rajendran, M.Sc. Nursing (2014-2016 Batch) student of Omayal Achi College of Nursing, Puzhal.This research study will evaluate **"A quasi experimental study to assess the effectiveness of Swedish massage on level of Chemotherapy Induced Nausea and Vomiting among children with cancer at selected Hospital, Surat".** If I and my child agree to participate in the study, we will be given structured interview schedule and medical record review will be done to know the demographic variables and my child will be given Swedish massage 24 hours and 30 minutes prior to chemotherapy and 24 hours after chemotherapy along with hospital routine. Then my child will be assessed for the level of CINV by using the Modified Rhodes Index of Nausea and Vomiting, 30 minutes prior to chemotherapy, 24 and 48 hours after chemotherapy. The answers will be kept confidential. No identifying information will be included during the analysis process. I understand that there are no risks associated with this study.

I comprehend that this study may help either my child or other children in the future. I realize that my child's participation in this study is entirely voluntary and I may withdraw my child from the study at any time we wish. If I decide to discontinue my child's participation in this study, my child will be continued to be treated in the usual and customary fashion.

I understand that all study data will be kept confidential. However, this information may be used in nursing publication or presentations. If I need to, I can contact Ms.Sowmiya Rajendran, M.Sc. Nursing (2014-2016 Batch) Omayal Achi College of Nursing, Puzhal phone no: 044-26591616, 17, 18 at any time during the study. The study has been explained to me. I have read and understood the assent form, my entire question has been answered, and I agree to allow my child to participate in the study. I understand that I will be given a copy of this signed consent form.

---------- ----------

Thumb print/Signature of Parent/Caregiver Date:

---------- ----------

Signature of Investigator Date

INFORMED ASSENT FORM

I _____ aged _____ understand that I am being asked to participate in a research study conducted by Ms. Sowmiya. Rajendran, M.Sc. Nursing (2014-2016 Batch) student of Omayal Achi College of Nursing Puzhal. This research study will evaluate **"A quasi experimental study to assess the effectiveness of Swedish massage on level of Chemotherapy Induced Nausea and Vomiting among children with cancer at selected Hospital, Surat".** If I agree to participate in the study, I will be given structured interview schedule and medical record review will be done to know the demographic variables and I will also be given Swedish massage 24 hours and 30 minutes prior to chemotherapy and 24 hours after chemotherapy along with hospital routine. Later, I will be assessed for the level of CINV by using the Modified Rhodes Index of Nausea and Vomiting, 30 minutes prior to chemotherapy, 24 and 48 hours after chemotherapy. The answers will be kept confidential. No identifying information will be included during the analysis process. I understand that there are no risks associated with this study.

I comprehend that this study may help either me or other children in the future. I realize that my participation in this study is entirely voluntary and I may withdraw from the study at any time I wish. If I decide to discontinue my participation in this study, I will be continued to be treated in the usual and customary fashion.

I understand that all study data will be kept confidential. However, this information may be used in nursing publication or presentations. If I need to, I can contact Ms.Sowmiya. Rajendran, M.Sc. Nursing (2014-2016 Batch) Omayal Achi College of Nursing, Puzhal phone no: 044-26591616,17,18 at any time during the study. The study has been explained to me. I have read and understood the consent form, my entire question has been answered, and I agree to participate in the study. I understand that I will be given a copy of this signed consent form.

---------- ----------

Thumb print/Signature of Parent/Caregiver Date:

---------- ----------

Signature of Investigator Date

APPENDIX – I

RESEARCH TOOL

PART 1- DEMOGRAPHIC DATA

Instructions: Choose appropriate option

1. Age in years
   a) 6-7
   b) 7-8
   c) 8-9
   d) 9-10

2. Gender
   a) Male
   b) Female

3. Religion
   a) Hindu
   b) Christian
   c) Muslim
   d) Others

4. Weight
   a) 16-20
   b) 21-25
   c) 26-30
   d) 31-35
   e) 36 and above

5. Height
   a) 110-120
   b) 121-130
   c) 131-140
   d) 141-150

6. Type of cancer

a) Acute Lymphocytic Leukemia
b) Acute Myeloid Leukemia
c) Hodgkin's lymphoma
d) Others

7. Duration of present chemotherapy

a) Below 1 week
b) 1-2 weeks
c) 2-3 weeks
d) 3-4 weeks
e) 4 weeks and above

8. Total number of cycles prescribed

a) 1
b) 2
c) 3
d) 4
e) 4 and above

9. n^{th} number of cycle

a) 1^{st}
b) 2^{nd}
c) 3^{rd}
d) 4^{th} and above

10. Type of chemotherapeutic agent

a) Highly emetogenic agents
b) Moderately emetogenic agents
c) Low emetogenic agents
d) Minimally emetogenic agents

11. Antiemetic drugs

    a) 5-HT_3 antagonist + Dexamethasone +Aprepitant
    b) 5-HT_3 antagonist+Dexamethasone
    c) 5-HT_3 or Dopamine antagonist
    d) Corticosteroid +Dexamethasone
    e) Others

12. Time of food consumption prior to chemotherapy

    a) Below 20 minutes
    b) 20-40 minutes
    c) 40-60 minutes
    d) Above 1 hour

13. Presence of caregiver during chemotherapy

    a) Present
    b) Absent

14. Previous history of cancer in family

    a) Present
    b) Absent

15. Home remedies

    a) Follows home remedies
    b) Does not follow remedies

MODIFIED RHODES INDEX OF NAUSEA AND VOMITING

KOREAN J ANESTHESIOL VOL. 52, NO. 6, JUNE, 2007

INDEX FOR NAUSEA AND VOMITING EVERY 24 HRS	SCORING					ANTICIPATORY CINV DAY-2 (BEFORE CHEMOTHERAPY)	ACUTE CINV DAY-3 (24 HOURS AFTER CHEMOTHERAPY)	DELAYED CINV DAY-4 (48 HOURS AFTER CHEMOTHERAPY)
	0	**1**	**2**	**3**	**4**			
1.In the last 24 hours I have felt nauseated or sick at my stomach( )	Not at all	1 hour or less	2-3hours	4-6 hours	More than 6 hours			
2. In the last 24 hours, I have felt nauseated or sick at my stomach ( ) times.	no	1-2 times	3-4 times	5-6 times	7 or more times			
3. In the last 24 hours, nausea has interfered with the activities of daily living.	no	Mild	moderate	great	severe			
4. In the last 24 hours, I don't feel like taking orally.	no	Iv fluids	Hospitalization	Tube feeding	TPN			
5. In the last 24 hours, I have had periods of severe nausea without bringing anything up ( ) times.	no	1-2 times	3-4 times	5-6 times	7 or more			
6. In the last 24 hours, I threw up ( ) times separated with interval of 5 minutes.	I did not throw up	1-2 times	3-4 times	5-6 times	7 or more times			
7. In the last 24 hours, each time I threw up I produced a ( ) amount.	I did not throw up	Small (upto1/2 cups)	Moderate (1\2-2 cups)	Large (2-3 cups)	Very large (3 or more cups)			
8. In the last 24 hours, I threw up $\geq$ 6 episodes separated by 5 minutes.	no	Iv fluids	Hospitalization	Tube feeding	TPN			

NOTE: THE INVESTIGATOR OBTAINED THE SCORES BASED ON THE RESPONSE GIVEN BY THE CAREGIVER / CHILD.

NOTE: The investigator has removed the component of retching from the original Rhodes index of nausea and vomiting.

Scoring key for Modified Rhodes Index of Nausea and Vomiting

	ITEMS ON SCALE	SCORE	TOTAL SCORE INTERPRETATION																					
					DAY-II (ANTICIPATORY CINV)					DAY – III (ACUTE CINV)					DAY – IV (DELAYED CINV)						ALL THE THREE DAYS CINV SCORES				
				TOTAL SCORE	NONE	MILD	MODERATE	GREAT	SEVERE	NONE	MILD	MODERATE	GREAT	SEVERE	NONE	MILD	MODERATE	GREAT	SEVERE	TOTAL SCORE	NONE	MILD	MODERATE	GREAT	SEVERE
NAUSEA EXPERIENCE	3,4	0-08	TOTAL NAUSEA SCORE	20	0	1-05	6-10	11-15	16-20	0	1-05	6-10	11-15	16-20	0	1-05	6-10	11-15	16-20	60	0	1-15	16-30	17-45	46-60
NAUSEA OCCURENCE	1,2,5	0-12																							
VOMITING EXPERIENCE	1,2,6, 8	0-16	TOTAL VOMITING SCORE	28	0	1-07	8-14	15-21	22-28	0	1-07	8-14	15-21	22-28	0	1-07	8-14	15-21	22-28	84	0	1-21	22-42	23-63	64-84
VOMITING OCCURENCE	6,7,8	0-12																							
TOTAL OCCURENCE	1,2,5, 6,7,8	0-24	TOTAL CINV SCORE	48	0	1-12	13-24	25-36	37-48	0	1-12	13-24	25-36	37-48	0	1-12	13-24	25-36	37-48	96	0	1-36	37-72	73-108	109-144
TOTAL EXPERIENCE	1,2,3, 4,6,8	0-24																							

APPENDIX – I

CODING FOR THE DEMOGRAPHIC VARIABLES

Demographic Variable	Code No.
1) Age in Years	
a) 6-7	1
b) 7-8	2
c) 8-9	3
d) 9-10	4
2) Gender	
a) Male	1
b) Female	2
3) Religion	
a) Hindu	1
b) Christian	2
c) Muslim	3
d) Others	4
4) Weight in kgs	
a) 16-20	1
b) 21-25	2
c) 26-30	3
d) 31-35	4
e) 36 and above	5
5) Height in cms	
a) 110-120	1
b) 121-130	2
c) 131-140	3

d) 141-150 4

6) Type of cancer

a) Acute Lymphocytic Leukemia 1

b) Acute Myeloid Leukemia 2

c) Lymphoma 3

d) Others 4

7) Total number of cycles prescribed

a) 1 1

b) 2 2

c) 3 3

d) 4 4

e) 4 and above 5

8) Duration of present chemotherapy

a) Below1 week 1

b) 1-2 weeks 2

c) 2-3 weeks 3

d) 3-4 weeks 4

e) 4 weeks and above 5

9) Type of chemotherapeutic agent

a) highly emetogenic agents 1

b) moderately emetogenic agents 2

c) low emetogenic agents 3

d) minimally emetogenic agents 4

10) Antiemetic drugs

a) 5-HT_3 antagonist + Dexamethasone +Aprepitant 1

b) 5-HT_3 antagonist+Dexamethasone 2

c) 5-HT_3 or Dopamine Antagonist 3

d) Corticosteroid +Dexamethasone 4

11) Time of food consumption prior to chemotherapy

a) Below 20 minutes 1

b) 20-40 minutes 2

c) 40-60 minutes 3

d) Above 1 hour 4

12) Type of diet consumed by the child prior to chemotherapy

a) Solid diet 1

b) Liquid diet 2

c) Bland diet 3

13) Presence of caregiver during chemotherapy

a) Present 1

b) Absent 2

14) Previous history of cancer in the family

a) Present 1

b) Absent 2

15) Home remedies

a) Follows home remedies 1

b) Does not follow remedies 2

APPENDIX – J

BLUE PRINT FOR DATA COLLECTION

S. No.	Content	Item	Total item	Percentage
1.	Demographic variables	1-16	16	100%
2.	Modified Rhodes Index of Nausea and Vomiting			
	Chemotherapy Induced Nausea	1-5	5	50%
	Chemotherapy Induced Vomiting	1,2,6,7,8	5	50%
	Total		10	100%

APPENDIX – K

INTERVENTION TOOL

Time : 20 minutes

Method : One to One method

Venue : Treatment room

SWEDISH MASSAGE:

Swedish massage is one of the simplest, non pharmacological and cost effective technique in reducing the level of CINV. It is a type of massage therapy referring to 5 gentle strokes applied from the lower back upto the shoulder of the children with cancer which makes them comfortable and enables them to perform their activities of daily living. It facilitates regulation within the body by decreasing the stimuli to CTZ and evokes a relaxation response. Swedish massage improves the sense of well being, decreases fatigue, pain, and anxiety ultimately improving the quality of life among children with cancer.

Preliminary preparation:

The investigator had given prior information to the parents and children that the intervention will be given to the child 24 hours and 30 minutes prior to chemotherapy and 24 hours after chemotherapy. The investigator obtained informed written consent from the parents/caregivers. The investigator then arranged the treatment room, prepared a bed with clean linen for the children to maintain privacy. The investigator performed the massage with or without the presence of the parents according to the child's choice. The investigator had performed hand hygiene and adorned face mask before handling the children following strict aseptic techniques.

During the procedure:

The child was asked to lie in prone position with their upper garment removed up to their waist and is covered with a bed sheet from the waist. After thorough hand washing the investigator begins the procedure by applying mild pressure on the child's skin. Then the investigator initiated the procedure of Swedish massage by using her palm, strokes the child from the buttocks up to the shoulder and then moves downward to the buttocks using less pressure. Then the investigator uses her thumb to oppose finger, knead and stroke the right half of the back using her right hand, knead and stroke the left half of the back using left hand. Starting from buttocks moving towards the child's shoulder and then again moving down the back. The investigator uses fleshy sides

(proximal) of her hands lightly striking the back from the buttocks up to the shoulder and repeats it. Next, the investigator uses the thumb pads or fingertips applying deep, circular movement near joints and other bony areas along the sides of the spine from the buttocks up to the spine of the child. Lastly, the investigator presses the child on the back and upper limbs, ends by rapidly shaking.

The following steps are discussed in the table given below:

Technique	Steps	Duration	Physiology
Effleurage	Long gliding strokes from the base of the spine to the shoulder.	4 minutes	Manipulation of muscles ↓ Modulate local blood flow, oxygen and lymph drainage. ↓ Influence neural activity (sub cortical nuclei) on CNS. ↔ Parasympathetic sympathetic nervous system. ↓ Innervates the GI tract ↓ Release endorphins, hormones, neurotransmitters. ↓ Reaches the limbic system, vomiting center and higher cortical centers of brain. ↓ Evoke relaxation response of muscles there by decrease stimuli to Chemoreceptor's trigger zone. ⇓ Reduction in level of CINV
Petrissage	Gently lifting muscles away from bone, then rolling and squeezing them again with gentle pressure from the base of the spine to the shoulder.	4 minutes	
Tapotment	Series of briskly applied percussive movements, using the hands alternately to strike or tap the muscles from the base of the spine to the shoulder.	4 minutes	
Friction	Most penetrating of all the strokes, and consists of deep circular or transverse movements made with the thumb pads or fingertips. The therapist applies deep, circular movement near joints and other bony areas (the sides of the spine) from the base of the spine to the shoulder.	4 minutes	
Vibration	Pressing hands on the back from the base of the spine to the shoulder, and ends by rapidly shaking for a few seconds.	4 minutes	
Total		20 minutes	

Post Procedure (After care): The children were dressed and then allowed to perform their routine activities.

Interpretation:

The level of CINV was assessed 3 days by using Modified Rhodes Index of Nausea and Vomiting for both the study and control groups. The first assessment was done 30 minutes prior to chemotherapy to assess the anticipatory episode of CINV, second assessment was done 24 hours after chemotherapy to assess the acute episode of CINV and finally third assessment was done 48 hours after chemotherapy to assess the delayed episode of CINV. CIN and CIV were scored separately and a cumulative of both for 3 days was the CINV score. The scores were interpreted by classifying them into none, mild moderate, great and severe.

APPENDIX – L

PROTOCOL ON SWEDISH MASSAGE

Definition:

A massage technique that includes effleurage, petrissage, friction, vibration, and tapotment. Swedish massage is intended to improve circulation and tissue elasticity while reducing muscle tone and creating a parasympathetic response.

-Medical Dictionary for the Health Professionals and Nursing (2012)

Purposes:

Circulatory system	• To increase circulation and elimination of metabolic wastes. • To improve lymphatic drainage.
Endocrine system	• To reduce pain by releasing endorphins, hormones. • To Support relaxation and improve sleep.
Musculoskeletal system	• To alleviates muscle tension and stiffness. • To delivers more oxygen which reduces muscle fatigue and soreness.
Respiratory system	• To stimulate slower breathing and break up mucus and respiratory discharge in the lungs. • To allow body to become relaxed and begin repairing process.
Digestive system	• To relieve colic and gas as well as constipation • To promote better digestion.
Psychological	• To relax body and mind. • To improve well being of the individual.

Indication:

→ Children undergoing chemotherapy.

→ Children experiencing Chemotherapy Induced Nausea , Chemotherapy Induced Vomiting and CINV and Chemotherapy Induced Retching.

→ Children undergoing chemotherapy experiencing severe pain, fatigue and anxiety, depression, eating disorders, stress.

Others:

→ Allergies, sleep problems, arthritis, bronchitis, sports injuries, cerebral palsy, Attention Deficit Hyperactivity Disorder (ADHD).

Contraindication:

→ Children diagnosed with psychosomatic disorders

→ Children with Gastrointestinal and Nervous system cancer

→ Wilm's tumor and any other mass or surgery in the abdominal area

→ Children using sedatives or opium drugs, Skin infections.

→ Children having sore and injury in the massage area, metastasis.

→ Children under radiation therapy.

→ Loss of consciousness.

General instructions for Swedish massage:

→ Practice strict aseptic technique to prevent cross infection.
→ Make sure that the linen spread is free from pathogens and clean.
→ Wash hands thoroughly before and after procedure.
→ Create a clean field around - avoid talking, coughing, sneezing to prevent cross infection.
→ Avoid Swedish massage if the child had meals less than 20 minutes prior to massage.
→ Remove any ornament if worn around the neck.
→ Inspect the back thoroughly before starting the procedure for any skin infection, masses or any unusual findings.
→ Keep the patient warm and comfortable with blankets, if necessary.
→ Swedish massage is to be performed using gentle strokes with mild pressure because vigorous massage has been associated with muscle pain and injuries such as bleeding in the liver and vital organs which might lead to severe complications.
→ Even though the last step of Swedish massage involves rapid shaking, nurses and caregivers must be alerted to perform it with mild pressure.
→ Only when the caregivers perform Swedish massage with adequate skill and gain expertise under strict guidance and supervision, they must be allowed to practice at home settings.

Preliminary Assessment:

→ Check the children's name, bed number and other identifications.
→ Check the diagnosis and age of the patient.
→ Check the consciousness of the patient and his ability to follow the instructions.
→ Check the general condition of the patient and willingness to participate.

Preparation of articles:

S.No.	Articles	Purpose
1.	Bed sheet -1	To cover the bed with clean linen.
2.	Soap/ hand washing solution -1	To wash hands in order to prevent infection.
3.	Hand sanitizer -1	To keep hands free from organisms.
4.	Mask -2	To prevent cross infection.
5.	Cap -2	To prevent cross infection.

Procedure:

Phase	Steps	Rationale
Preliminary Preparation	→ Place the child prone position with their upper garment removed upto the waist. → Perform hand hygiene and dry using sterile towel or tissue paper. → Wear personal protective equipment such as face mask and cap. → Warm hands by rubbing palm against palm.	→ To provide comfort to the child. → To prevent infection. → To prevent cross infection. → To provide warmth to the child.
Procedure	→ Apply mild pressure from the buttocks up to the shoulder and then move downward to the buttocks using 5 main strokes as follows : ➢ Effleurage - Long gliding strokes from the base of the spine to the shoulder. ➢ Petrissage- Gently lift the muscles away from bone, then roll and squeeze them again with gentle pressure from the base of the spine to the shoulder. ➢ Tapotment - Use the hands alternately to strike or tap the muscles from the base of the spine to the shoulder. ➢ Friction- Apply deep, circular transverse movements using thumb pads or fingertips near joints and other bony areas (the sides of the spine) from the base of the spine to the shoulder. ➢ Vibration- Press hands on the back	→ To prevent complications such as bleeding, pain etc. → The rationale behind the steps are as follows: Manipulation of muscles modulates local blood flow, oxygen and lymph drainage. Influence neural activity (sub cortical nuclei) on CNS. Parasympathetic sympathetic nervous system. Innervates the GI tract Release endorphins, hormones, neurotransmitters. Reaches the limbic system, vomiting center and higher cortical centers of brain. Evoke relaxation response of muscles there by decrease stimuli to CTZ. Reduce the level of CINV

Phase	Steps	Rationale
	from the base of the spine to the shoulder, and end by rapidly shaking for a few seconds.	
Post procedure- (After care)	→ Dress the child and allow toperform daily activities. → Wash your hands. → Document the procedure.	→ To prevent infection. → To identify the present condition of the child.

When to stop:

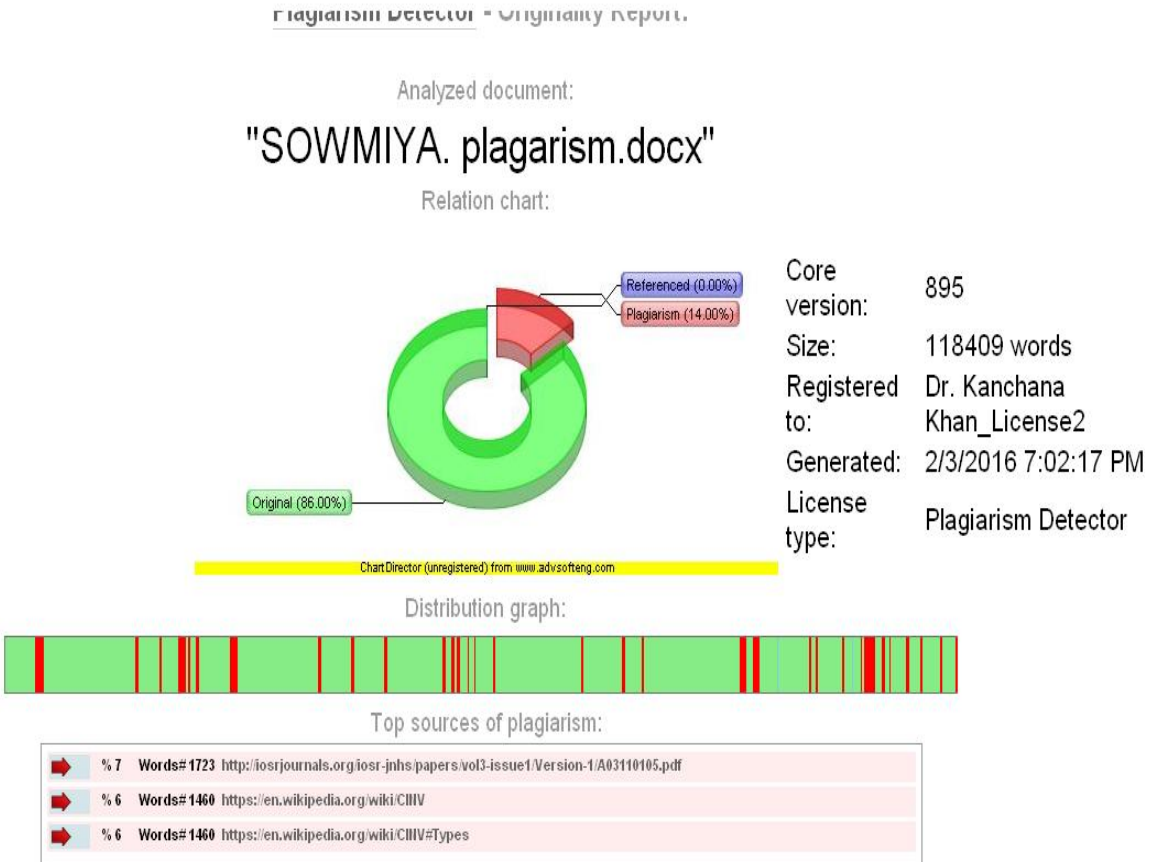
⚠ Nursing Alert:

! There are few reported side effects associated with massage, however,

→ If the child refuses to continue Swedish massage, feels uncomfortable and alterations in vital signs are evident then, immediately the nurse or caregiver must stop the procedure.

APPENDIX - M

PLAGIARISM REPORT

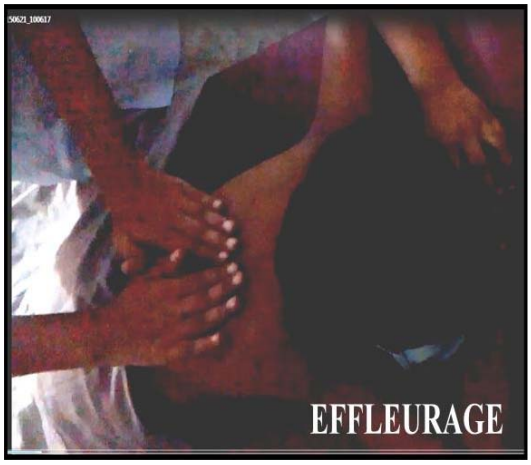


APPENDIX – J

DISSERTATION EXECUTION PLAN - GANNT CHART																			
S.NO	**CALANDER MONTHS**	**Nov '14**	**Dec '14**	**Jan '15**	**Feb '15**	**Mar '15**	**Apr '15**	**May '15**	**June '15**	**July '15**	**Aug '15**	**Sep '15**	**Oct '15**	**Nov '15**	**Dec '15**	**Jan '16**	**Feb '16**	**Mar '16**	**Apr '16**
A	**Conceptual phase**																		
1	Problem identification																		
2	Literature review																		
3	Clinical fieldwork																		
4	Theoretical framework																		
5	Hypothesis formulation																		
B	**Design & planning phase**																		
6	Research design																		
7	Intervention protocol																		
8	Population specification																		
9	Sampling plan																		
10	Data collection plan																		
11	Ethics procedure																		
12	Finalization of plans																		
C	**Empirical phase**																		
13	Data collection																		
14	Data preparation																		
D	**Analytical phase**																		
15	Data analysis																		
16	Interpretation of results																		
E	**Dissemination phase**																		
17	Presentation or report																		
18	Utilization of findings																		
	Calendar months	**11**	**12**	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	09	10	11	12	13	01	02	**03**

APPENDIX – O

PHOTOGRAPHS



Oral informed consent was obtained to publish the photographs in the dissertation.

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